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B 862

May 13, 2019

Richard Bonnette
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Campus Drive
College Park, MD 20740-3835

Subject: GRAS Notification – DHA Algal Oil and Powder

Dear Mr. Bonnette:

On behalf of BASF Corporation, ToxStrategies, Inc. (its agent) is submitting, for FDA review, a copy of the GRAS notification as required. The enclosed document provides notice of a claim that the food ingredient, algae-sourced DHA oil and powder, described in the enclosed notification is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be generally recognized as safe (GRAS), based on scientific procedures, for addition to food and infant formula.

In addition, the data and information in the GRAS notice can be shared with the Food Safety Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). Algal oil derived from *Schizochytrium* sp. is on the safe and suitable list (https://www.fsis.usda.gov/wps/wcm/connect/ce40e7ae-3d55-419e-9c68-a1b6fefcd4de/7120.1_Table_2.pdf?MOD=AJPERES), and as such, will be used as an alternative edible oil in the production of various meat and poultry products at levels not to exceed 1.45% by weight of the product formulation for meat products and 0.87 % by weight of the product formulation for poultry products.

If you have any questions or require additional information, please do not hesitate to contact me at 630-352-0303, or dschmitt@toxstrategies.com.

Sincerely,

[redacted]

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc., 931 W. 75th St., Suite 157, PMB 255, Naperville, IL 60565
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GRAS Determination of DHA Algae-Sourced Products (Oil and Encapsulated Powder Forms) for Use in Foods and Infant Formula

MAY 13, 2019

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GRAS Determination of DHA Algae-Sourced Products (Oil and Encapsulated Powder Forms) for Use in Foods and Infant Formula

SUBMITTED BY:

BASF Corporation
Nutrition and Health
100 Park Avenue
Florham Park, NJ 07932

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
5100 Campus Drive
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

Donald F. Schmitt, MPH
ToxStrategies, Inc.
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Naperville, IL 60565

MAY 13, 2019

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List of Acronyms

ARA	arachidonic acid
ARASCO	arachidonic acid single cell oil
ASD	autism spectrum disorder
ATCC	American Type Culture Collection
BSID	Bayley Scales of Infant and Toddler Development
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CFU	colony-forming unit
cGMP	current Good Manufacturing Practices
CRP	C-reactive protein
COA	Certificate of Analysis
CP	cerebral palsy
DHA	docosahexaenoic acid
DHASCO	docosahexaenoic acid single cell oil
DRM	DHA-rich microalgae
EC	European Commission
EDI	estimated daily intake
EE	ethyl ester
EFSA	European Food Safety Authority
EGFR	epidermal growth factor receptor
EPA	eicosapentaenoic acid
EU	European Union
FA	fatty acid
FAO	Food and Agricultural Organization
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
FR	Federal Register
FSIS	Food Safety and Inspection Service
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
HM	human milk
HMF	human milk fortifier
IOM	Institute of Medicine
JECFA	Joint FAO/WHO Expert Committee on Food Additives
KOH	potassium hydroxide
LCPUFA	long-chain polyunsaturated fatty acids
LD50	median lethal dose
MCT	medium chain triglycerides
meq	milliequivalents
mM	millimolar
NA	not available
NaCl	sodium chloride
ND	not detected

NOAEL	no-observed-adverse-effect level
ONC	Ocean Nutrition Canada Limited
PBS	phosphate-buffered saline
PC	phosphatidylcholine
PE	phopshatidylethanolamine
PUFA	polyunsaturated fatty acids
ROP	retinopathy of prematurity
SSU-rDNA	small subunit ribosomal DNA
TG	triglyceride
UK	United Kingdom
UL	tolerable upper intake level
USDA	United States Department of Agriculture
VMI	visual-motor integration
WHO	World Health Organization

§ 170.225 Part 1, GRAS Notice: Signed Statements and Certification

(1) GRAS Submission

BASF Corporation (BASF), through its agent ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the determination of a Generally Recognized as Safe (GRAS) notice for the use of docosahexaenoic acid (DHA) algae-source products (oil and encapsulated powder forms) in foods and infant formula in accordance with Subpart E of 21 CFR § 170.

(2) Name and Address

BASF Corporation
Nutrition and Health
100 Park Avenue
Florham Park, NJ 07932

(3) Name of Notified Substance

The name of the substance that is the subject of this GRAS determination is DHA algae-sourced oil and powder forms from the wild-type heterotrophic microalgae *Schizochytrium* sp. ONC-T18 (hereinafter referred to as T18).

(4) Intended Use in Food

The DHA algal oils and powders are intended for use as direct food ingredients in 1) foods and 2) non- exempt and pre-term exempt infant formula, in accordance with current good manufacturing practices (cGMP), and in combination with a source of arachidonic acid (ARA). The ratio of DHA to ARA would range from 1:1 to 1:2. The intended use level is similar to all other approved uses for incorporation of DHA in infant formula. BASF does not manufacture infant formula. The company only manufactures DHA algal oil and powder ingredients for use in food, including infant formula. As such, they provide an alternative source of DHA for incorporation in food, including infant formula. Therefore, it is envisioned that BASF's DHA ingredients could be used in any exempt (preterm or term) or non-exempt formula that contains DHA.

(5) Statutory Basis for GRAS Determination

BASF, through its agent ToxStrategies, Inc., hereby notifies FDA of the submission of a GRAS notice for DHA algal oils and powders, meeting the specifications described herein, has been determined to be GRAS through scientific procedures in accordance with 21 CFR § 170.30(a) and (b).

(6) Premarket Approval Statement

BASF further asserts that the use of the DHA algal oils and powders, as described below, are exempt from pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act based on a conclusion that the substances are GRAS under the conditions of their intended use.

(7) Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent on request, or are available for the FDA's review and copying during customary business hours from ToxStrategies, Inc., Naperville, IL. Please contact Donald F. Schmitt, ToxStrategies (agent for BASF) for all technical or regulatory information.

(8) Data and Information Confidentiality Statement

None of the data and information in the GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

(9) GRAS Certification

To the best of our knowledge, the GRAS determination is a complete, representative, and balanced review. BASF is not aware of any information that would be inconsistent with a finding that the proposed use of the DHA-rich algal oil and powder in foods and infant formula (pre-term and term infants), meeting appropriate specifications, and used according to cGMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

(10) Name/Position of Notifier

May 13, 2019

Haresh P. Madeka, Ph.D.
Senior Regulatory and External Affairs Manager
Human Nutrition
BASF Corporation

Date

(11) FSIS Statement

The data and information in the GRAS notice can be shared with the Food Safety Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). The DHA algal oil and powders will be used as an alternative edible oil in the production of various meat and poultry products at levels not to exceed 1.45% by weight of the product formulation for meat products and 0.87 % for poultry products. DHA Algal oil derived from Schizochytrium sp. is on the USDA/AMS safe and suitable list.

§ 170.230 Part 2, Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

Identity

The DHA products that are the subject of this GRAS determination are in either oil or powder forms. The oil is a clear to turbid, light yellow to orange liquid oil that is manufactured by fermentation from the microalgae *Schizochytrium* sp. ONC-T18 (hereinafter referred to as T18), followed by separation from the alga biomass and subsequent refining which results in a refined oil suitable for human consumption. It is a mixture of triglycerides containing mostly polyunsaturated fatty acids (PUFA) in which the predominant fatty acid (approximately 40%) is DHA. The encapsulated powders are spray-dried, free-flowing forms of the algal oil.

Empirical Formula and Chemical Structure of DHA

The empirical formula for DHA is C22H32O2. The systematic name is 4,7,10,13,16,19-docosahexaenoic acid, and is often written as 22:6n-3 where the numbers indicate the number of carbon atoms in the molecule (22), the number of double bonds (6), and the number of carbon atoms from the methyl terminus to the first double bond (3). The molecular weight of DHA is 328.488 g/mol. The structural formula for DHA is represented below in Figure 1.

Figure 1. Structural formula of DHA

Common or Chemical Names

The preparation under consideration is referred to as: DHA algal oil, DHA-rich algal oil, *Schizochytrium* sp. oil, omega-3-rich algal oil, omega-3 algal oil, algal oil, dry DHA algal powder. CAS No. 68424-59-9; glycerides, C14-C22 and C16-C22 unsaturated.

Trade Names

DHA Algal Oil, Dry n-3™ DHA Algal Powder.

Characterization of Strain

Schizochytrium sp. are part of the human food chain and they are consumed as a function of eating mussels and clams as well as other marine organisms in general (Hammond et al., 2002). The *Schizochytrium* strain used is naturally occurring and not a product of genetic engineering. The micro-algal family *Thraustochytriaceae* has historically comprised seven genera, *Japanochytrium, Schizochytrium, Ulkenia, Althornia, Diplophrys, Aplanochytrium,* and *Thraustochytrium*, all of which are referred to as

thraustochytrids. Under this classification scheme, strain T18 had previously been assigned to the genus *Thraustochytrium* (Burja et al., 2006). The genera *Thraustochytrium, Schizochytrium and Ulkenia* (oils from the latter two are the subject of previous authorizations under European Union (EU) novel food regulations and are GRAS (FDA, 2010, 2014a)) comprise marine protists commonly found in marine and estuarine environments.

The taxonomic structure of the family *Thraustochytriaceae* has been the subject of discussion and subsequent redistribution of some of the component organisms into a broader suite of genera, including members of the genus *Schizochytrium* (Yokoyama and Honda, 2007a) and the genus *Ulkenia* (Yokoyama et al., 2007b). As reported in a 2011 substantial equivalence submission to the (United Kingdom) UK Food Standards Agency (ONC, 2011), the former Ocean Nutrition Canada Limited (ONC) commissioned an expert review of the relationship between its thraustochytrid strain T18 and *Schizochytrium* sp. ATCC 20888, the parent wild-type strain that was the basis of Commission authorization decision 2003/427/EC. On the basis of morphological characteristics, pigment and fatty acid profiles, and a comparison of small subunit ribosomal DNA (SSU-rDNA) sequences of the two organisms, it was concluded that the two strains were closely related, and the strain T18 was more appropriately considered as falling within the genus *Schizochytrium sensu lato*. In 2012, the UK Food Standards Agency concluded that ONC's algal oil met the criteria for equivalence as defined in Article 3(4) of regulation (EC) 258/97 and that the *Schizochytrium* strain used by ONC was closely related to the organism used in the production of a Martek algal oil (Food Standards Agency, 2012).

The possible presence of microalgae toxins produced by *Schizochytrium* sp. has been previously addressed as part of the substantial equivalence submission referenced above and in GRAS Notification (GRN) No. 553 (FDA, 2014a). Toxin production is unlikely since there are no known reports of toxin production by thraustochytrids, of which *Schizochytrium* is a member (ONC, 2011; Hammond et al., 2002). In addition, T18 oil and algal biomass were screened for the presence of toxins including domoic acid, gymnodimine, desmethyl spirolide C, azaspiracid-1, azaspiracid-2, azaspiracid-3, pectenotoxin-2, okadaic acid, dinophysistoxin-1, dinophysistoxin-2, yessotoxin, prymnesin-1, and prymnesin-2, and none were detected (ONC, 2011).

Manufacturing Process

The following are descriptions of the processes used to manufacture the crude algal oil and then refine the DHA algal oil isolated from the fermentation process (see Figures 2 and 3). The process steps employed to refine the crude algal oil are similar to what is practiced in the refining of vegetable oils.

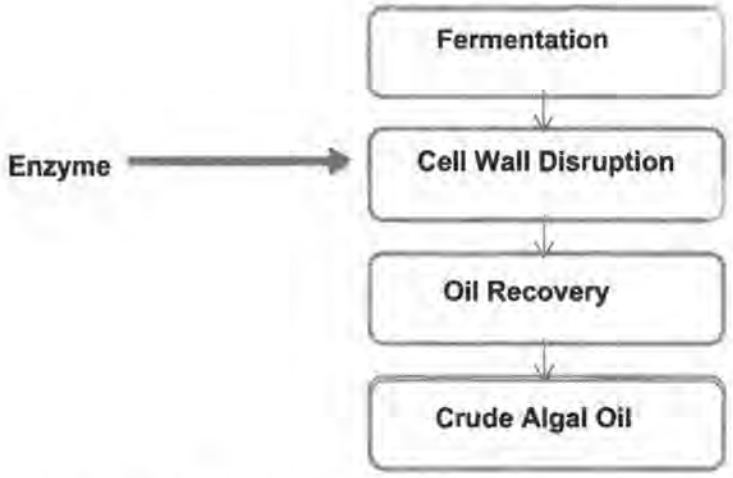

Figure 2. Crude DHA algal oil production

As summarized in GRN 677, an oil rich in PUFA is produced by a heterotrophic fermentation process with a single cell marine microalgae of the genus *Schizochytrium*, in particular, T18 (GRN 677; FDA, 2016). The fermentation process uses a medium containing carbon and nitrogen sources, bulk and trace mineral nutrients, and vitamins (see Table 1, GRN 677). The microorganism T18 is maintained on nutrient agar plate before production. Following inoculation of the microorganism into a shake flask, the cultivation process is scaled up through multiple stages of transfers, and finally into the production fermentation vessel. All vessels, pipelines, and fermentation media are subjected to a rigorous, timed, and controlled sterilization process prior to the transfer of the microorganism. The fermentation is carried out under axenic conditions (i.e., only one organism present, T18). During the fermentation process, more sterile carbon substrate (i.e., dextrose) is added to the fermenter to allow higher cell growth and more oil synthesis. Operating parameters such as temperature, pH, aeration, and agitation are controlled throughout the process to ensure that results, in terms of cell growth, oil synthesis, and the oil's fatty acid profile, are reproducible. The vessel is operated under positive pressure to prevent any contamination by foreign organisms.

Once fermentation is complete (i.e., as determined by carbon usage, cell growth, oil synthesis activity, and oil fatty acid profile), the crude oil that accumulates intracellularly is recovered from the fermentation broth via an aqueous extraction process. To release the oil from the cells, the cell wall requires disruption. In the cell wall disruption process, the fermentation broth is pH adjusted with sodium hydroxide and hydrolyzed enzymatically. As a result, no intact algae remain in the oil. The oil is then recovered from the hydrolyzed biomass. In the oil recovery process, the hydrolyzed biomass can be treated and centrifuged to yield the crude algal oil. At each step after cell wall disruption, exposure to air is minimized. Antioxidants (e.g., mixed tocopherols; CAS No. 1406-18-4) can be added. The manufacturing process is represented schematically in Figure 2 and is essentially the same as that described for the production of the currently authorized oil from *Schizochytrium* sp. (DHA-B) (FDA, 2014a). BASF's source of crude algal DHA oil has been known to FDA or is a subject of other GRAS notifications (e.g., GRN 677).

Figures 3 and 4 represent the DHA algal oil and dry n-3® DHA Algal Powder manufacturing processes and are followed by a narrative description of the refining steps employed in the production of both products.

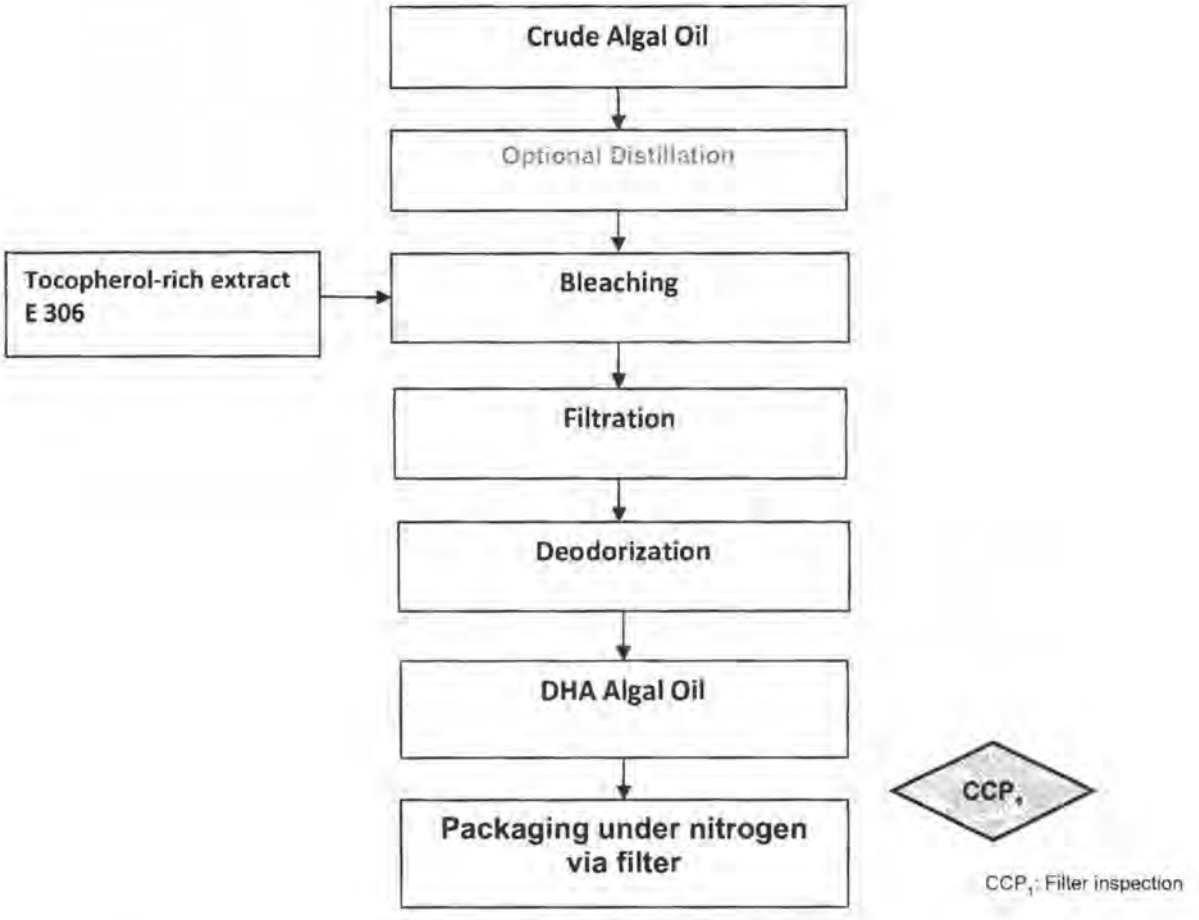

Figure 3. DHA algal oil refining process

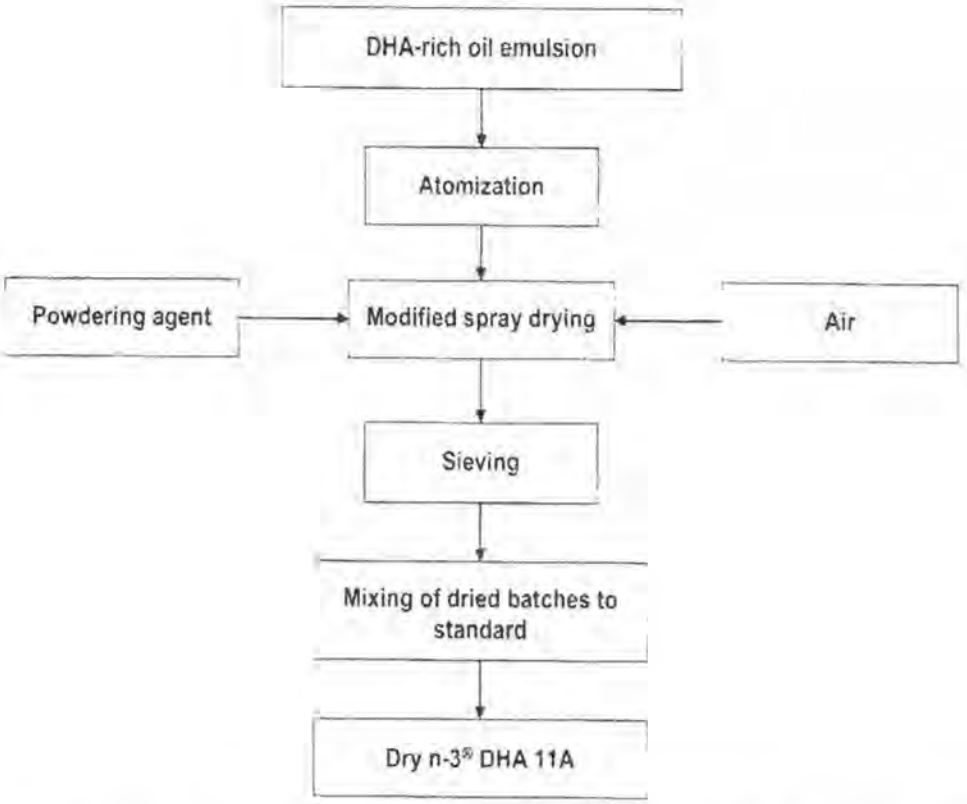

Figure 4. DHA algal oil powder process – Dry n-3 DHA 11A as an illustration

Distillation (Optional Process)

The oil is distilled at high temperatures under very low pressure. Under these conditions, free fatty acids, environmental pollutants and free sterols are removed. This process is optional, and it is only applied in case that the crude oil contains higher levels of free fatty acids or sterols which cannot be removed by the subsequent refining processes.

Bleaching

Bleaching is a standard process in vegetable oil refining. This process removes unwanted oxidation by-products and environmental pollutants. This process also binds color pigments and yields into a lighter colored oil. During this process the oil is protected by nitrogen and by the addition of tocopherol-rich extract (antioxidant E306 / mixed tocopherols) against oxidation. The algal oil is mixed with activated carbon, bleaching earth (also called diatomaceous earth or silicates) and filter aid (silicates). It is kept under

agitation at hot conditions for a defined time. Afterwards the bleaching earth, filter aid and activated carbon are removed by filtration.

Deodorization
The bleached algal oil is further refined by deodorization to yield a fully refined oil with mild sensory attributes. In this process the oil is passed through a deodorizer column at hot temperatures and under reduced pressure. Steam is flushed against the oil stream. Volatile substances are removed under these conditions. The refined algal oil product is then packaged in drums under nitrogen and subsequently warehoused.

Spray-drying/micro-encapsulation

The refined algal oil is blended with oil miscible antioxidants and emulsifiers and then homogenized with the water-phase containing the water-dispersible ingredients, including carbohydrates and protein. The resulting emulsion is afterwards spray-dried and micro-encapsulated using corn starch. For further details on formulation ingredients and processing aids please refer to Table 2 and the manufacture flowchart (Figure 4).

Packaging

The finished powder product is filled/packed under nitrogen into composite foil bags with a carton box as outer packaging.

All raw materials and processing aids are purchased according to defined specifications and from qualified and approved suppliers. Raw materials and processing aids are analyzed according to defined quality standards. Tables 1 and 2 provide overviews of the raw materials and processing aids used in the manufacture of the DHA Algal oil and encapsulated powder products. All of the processing aids are removed within the production process.

Table 1. Raw materials and processing aids used in production of DHA algal oil(s)

Material	Category	Used in Manufacturing Step
Crude algal oil	Raw material	Bleaching
Tocopherol-rich concentrate E 306	Antioxidant	Bleaching
Bleaching earth/silica	Processing aid	Bleaching
Activated carbon	Processing aid	Bleaching
Filter aid	Processing aid	Bleaching
Filter	Processing aid	Filtration
Steam	Processing aid	Deodorization
Nitrogen	Processing aid	Bleaching & Packaging

Table 2. Formulation ingredients and processing aids used in production of DHA algal powder(s)

Material	Category	Used in Manufacturing Step
Refined algal oil	Raw material	Oil phase
Tocopherol-rich concentrate E 306	Antioxidant	Oil phase
Ascorbyl palmitate E 304	Antioxidant	Oil phase
Mono- and diglycerides of fatty acids E 471	Formulation aid	Oil phase
Lecithins E 322 (from soy bean sources)	Formulation aid	Oil phase
Potable water	Processing aid	Water phase
Glucose syrup	Formulation ingredient	Water phase
Edible acid casein (solubilized with potassium hydroxide)	Formulation ingredient	Water phase
Sodium ascorbate E 301	Antioxidant	Water phase
Corn starch	Formulation ingredient	Micro-encapsulation
Tricalcium phosphate E 341	Free-flowing agent	Micro-encapsulation
Nitrogen	Processing aid	Packaging

Note: all of the above components are safe and suitable and commonly used in infant formula.

Product Specifications

The specifications for the BASF's DHA-rich oil from *Schizochytrium* sp. T18 manufactured by the processes outlined above are found in Table 3. The micro-encapsulated algal powder, high in polyunsaturated fatty acids, predominantly DHA (≥ 150 mg/g) contains only traces of water (typically less than 3%). It is a spray-dried, micro-encapsulated version of the DHA algal oil described in the specifications found in Table 4. Analytical results for four lots of the proposed BASF DHA algal oil can be found in Table 5 and Appendix A. Analytical results for BASF DHA algal powder can be found in Appendix A.

Table 3. Specifications for BASF DHA algal oil

Parameter	DHA Algal Oil
Appearance	Clear to turbid, yellow to orange liquid
Acid value (mg KOH/g)	≤ 0.5
Peroxide value (meq O^2/kg)	≤ 4.0
Anisidine value	≤ 15
Unsaponifiable matter (weight %)	≤ 3.5
Moisture (weight %)	≤ 0.05
DHA (mg/g as triglyceride)*	≥ 380
Trans fatty acids (area-%)	≤ 1.0
Iron (Fe) (mg/kg)	≤ 0.2
Copper (Cu) (mg/kg)	≤ 0.05

*It is possible in the future that a DHA algal oil and powder of lower potency, such as 35% DHA in algal oil and 11% in powder, could be manufactured and used accordingly by infant formula manufacturers.

Table 4. Specifications for BASF DHA algal powder(s)

Parameter	DHA Algal Powder
DHA (as triglycerides), % (w)	≥ 10.5
DHA (as fatty acids), % (w)	≥ 10
Appearance	Light yellow to light beige free flowing spray-dried powder
Particle size distribution Through mesh 20 USP (%) Through mesh 40 USP (%) Through mesh 120 USP (%)	 100 ≥ 90 ≤ 12
Loss on drying (105°C) (%)	≤ 5
Peroxide value (meq/kg)	≤ 2
Anisidine value	≤ 15
Free fat (%)	≤ 1.0
Lead (ppm)	≤ 0.02
Cadmium (ppm)	≤ 0.01
Mercury (ppm)	≤ 0.02
Arsenic (ppm)	≤ 0.1
Total aerobic mesophilic plate count (TAMC) (cfu/g)	≤ 1000
Total combined yeasts and moulds (TYMC) (cfu/g)	≤ 30
*Salmonella**	Absence in 30*25g
Staphylococcus aureus	Absence in 10g
Bacillus cereus (cfu/g)	≤ 100
E. sakazakii (*Cronobacter* spp)*	Absence in 300g
Enterobacteria	Absence in 5*5g
Escherichia coli	Absence in 10g
Pseudomonas aeruginosa	Absence in 10g
Sulphite reducing *Clostridia* (cfu/g)	≤ 10
Clostridium perfringens (cfu/g)	≤ 10

* *Salmonella* and *Cronobacter* spp. specifications are more stringent and specific to infant formula use, but not food uses (i.e., 30*25g and 300g, respectively).

Table 5. Analytical results for four lots of BASF DHA algal oil compared to product specifications

Parameter	DHA Algal Oil	DHA Algal Oil	DHA Algal Oil	DHA Algal Oil	DHA Algal Oil
Sample Number	**Specifications**	**DH5750**	**DH5751**	**DH5752**	**0016888247**
Appearance	Clear to turbid, yellow to orange liquid	complies	complies	complies	complies
Acid value (mg KOH/g)	≤ 0.5	0.04	0.02	0.04	0.1
Peroxide value (meq O^2/kg)	≤ 4.0	0.5	0.6	0.5	<0.1
Anisidine value	≤ 15	1.5	1.6	1.9	3
Unsaponifiable matter (weight %)	≤ 3.5	0.8	0.09	0.8	1.6
Moisture (weight %)	≤ 0.05	<0.01	<0.01	<0.01	0.02
DHA (mg/g as triglyceride)	≥ 380	444	441	394	403
Trans fatty acids (area-%)	≤ 1.0	0.1	0.1	0.1	0.1
Iron (Fe) (mg/kg)	≤ 0.2	<0.1	<0.1	<0.1	<0.1
Copper (Cu) (mg/kg)	≤ 0.05	<0.01	<0.01	<0.01	<0.05

As seen in Table 6 below, all the fatty acids detected are well-known components of the human diet and are found in both animal and vegetable food sources. The data are presented as % of total fatty acids. The major fatty acids in the DHA algal oil product are DHA, myristic acid, palmitic acid, and docosapentaenoic acid. When compared to the spectrum of available DHA oils from a variety of sources, including algae and fish that are used in food, the fatty acid profiles of the proposed DHA algal oil is comparable to currently marketed DHA oil products, as well as other commercially available oils (FDA, 2000, 2014a, 2016).

Table 6. Fatty acid profile for BASF DHA algal oil

Fatty Acids		DHA Algal Oil [Area %]			
		DH5750	**DH5751**	**DH5752**	**0016888247**
12:0	Lauric acid	0.8	0.9	0.9	1.0
13:0	Tridecanoic acid	0.1	0.1	0.1	0.1
14:0	Myristic acid	9.1	9.7	9.8	10.2
14:1	Myristoleic acid	0.1	ND	0.1	0.1
15:0	Pentadecanoic acid	0.4	0.5	0.3	0.5
16:0	Palmitic acid	20.8	22.3	18.5	22.3
16:1	Palmitoleic acid	4.1	2.9	6.6	3.9
17:0	Heptadecanoic acid	0.1	0.2	0.1	0.2
18:0	Stearic acid	0.7	0.8	0.7	0.8
18:1 (trans)	Oleic acid, trans	0.1	ND	0.1	ND
18:1 (n-9)	Oleic acid, cis	7.0	6.1	10.3	7.1
18:2 (n-6)	Linoleic acid	0.5	0.6	0.5	0.6
18:3 (n3)	Alpha-Linolenic acid	0.2	0.2	0.2	0.2
20:0	Arachidic acid	0.1	0.1	0.1	0.1
20:1	Eicosenoic acid	0.4	0.4	0.6	0.5
20:3 (n-6)	Dihomo gammalinolenic acid	0.1	0.1	0.1	0.1
20:4 (n-6)	Arachidonic acid	0.3	0.3	0.2	0.3
20:5 (n-3)	Eicosapentaenoic acid EPA	1.6	1.7	1.5	1.7
22:5 (n6)	Docosapentaenoic acid DPA	8.1	7.8	7.2	7.7
22:5 (n-3)	Docosapentaenoic acid DPA	0.3	0.4	0.3	0.3
22:6 (n-3)	Docosahexaenoic acid DHA	44.5	44.2	41.1	41.7
Sum		**99.4**	**99.3**	**99.3**	**100**

ND – not detected

The sterol content of the proposed DHA algal oil was also determined (see Table 7). The detected sterols and stanols are also present in the human diet from vegetable and animal food sources such as common edible oils. The sterol levels presented in Table 7 for the proposed DHA algal oil, are lower as a total than the other oils, and under the intended conditions of use, the total sterol intake from DHA algal oil would be minimal. Additionally, the sterol profile of the proposed DHA algal oil is similar to that found in other algal oils and fish oils that are currently used in food including infant formula (FDA, 2000; FDA, 2014a).

Table 7. Sterol content and sterol isomers of BASF DHA algal oil

Parameter		DHA Algal Oil		
	DH5750	DH5751	DH5752	0016888247
Cholesterol (%)	13.1	13.7	11.7	29.8
Brassicasterol (%)	5.6	4.0	6.3	3.9
Campesterol (%)	3.8	4.2	3.4	4.8
Stigmasterol (%)	19.6	14.1	24.0	13.7
Delta-7-Campesterol (%)	0.3	0.9	0.4	0.5
Delta-5,23 Stigmastadienol (%)	1.6	1.3	1.7	0.9
Chlerosterol (%)	20.3	15.8	17.0	9.6
Beta-Sitosterol (%)	14.8	16.0	19.1	21.1
Beta-Sitostanol (%)	-	-	-	2.4
Delta-5 Avenasterol (%)	1.3	2.9	3.2	1.4
Delta-5,24 Stigmastdienol (%)	8.9	10.4	6.0	5.2
Delta-7 Stigmastenol (%)	7.3	13.1	5.2	5.1
Delta-7 Avenasterol (%)	3.3	3.7	1.9	1.6
Total sterols (mg/kg)	705	1020	1210	2843

It should be noted that numerous other analyses of the proposed DHA algal oil product have been conducted but are not included in the product specifications (e.g., microbiological contaminants such as coliform bacteria, *Escherichia coli*, Enterobacteriaceae, yeast, molds, *Salmonella*, *Staphylococci coagulase*, *Pseudomonas aeruginosa*; heavy metals-arsenic, cadmium, lead, mercury; other inorganic impurities such as chromium, manganese, molybdenum, nickel, phosphorous, silicon, and sulfur; dioxins and furans- polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans; dioxin-like polychlorinated biphenyls (PCBs); pesticides; polycyclic aromatic hydrocarbons (PAHs) and benzo(a)pyrene; algal toxins (ASP-toxin, domoic acid; okadaic acid; PSP-toxin, saxitoxin; DTX-1); mycotoxins; phthalates; 3-monchloro propane diol ester (3-MCPD) and glycidyl esters. Results of these additional analyses are included in Appendix A and selected results are summarized in Table 8 below. In summary, the analytical results confirm that the finished DHA algal oil and powder products meet the analytical specifications and confirm the lack of levels of impurities/contaminants of toxicological concern.

Table 8. Select Analytical Results for Residual Contaminants in BASF DHA algal oil

Elemental Analysis				
	DH5750	**DH5751**	**DH5752**	**016888247**
Arsenic (ppm)	<0.1	<0.1	<0.1	<0.1
Cadmium (ppm)	<0.01	<0.01	<0.01	<0.01
Lead (ppm)	<0.02	<0.02	<0.02	<0.05
Mercury (ppm)	<0.005	<0.005	<0.005	<0.005
Chromium (ppm)	<0.05	<0.05	<0.05	NA
Manganese (ppm)	<0.1	<0.1	<0.1	NA
Molybdenum (ppm)	<0.2	<0.2	<0.2	NA
Nickel (ppm)	<0.1	<0.1	<0.1	NA
Phosphorus (ppm)	<3	<3	<3	NA
Silicon (ppm)	13	22	28	NA
Sulfur (ppm)	<2	3.0	<2	NA
Microbiological Analyses				
Salmonella sp.	Negative/25g	Negative/25g	Negative/25g	Negative/25g
Escherichia coli	Negative/g	Negative/g	Negative/g	NA
Enterobacteriaceae	Negative/g	Negative/g	Negative/g	Negative/g
Total aerobic mesophilic count	<10	<10	<10	<10
Staphylococci coagulase pos.	Negative/g	Negative/g	Negative/g	Negative/g
Pseudomonas aeruginosa	Negative/g	Negative/g	Negative/g	Negative/g
Yeasts	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g
Molds	<10 CFU/g	<10 CFU/g	<10 CFU/g	NA
Coliform bacteria	Negative/g	Negative/g	Negative/g	NA
Other Residuals				
Benzo(a)pyrene (ppb)	<0.5	<0.5	<0.5	<0.5
Sum NDL-PCB 6 (ppm)*	<0.980	<0.987	0.951	1.89
Sum PAH 4 (ppb)	<0.5	<0.5	<0.5	<0.5

NA – not available

- Individual PCBs below level of detection of 0.16 ppb for batches 1-3 and 0.31 ppb for batch 4

Stability Data

DHA Algal Oil

DHA algal oil is a triglyceride oil high in polyunsaturated fatty acids, predominantly consisting of DHA. The product contains only traces of water (<0.05%; aw value ≤0.4 analyzed in analogue omega-3 oils). Due to this low water activity, the shelf life of the product is neither limited by hydrolysis (increase in acid value) nor by microbiological growth or spoilage. The shelf life of this product is therefore only limited by oxidation. DHA algal oil is protected by several means against such oxidation. A tocopherol-rich extract is added during the manufacturing process. The oil is packed into inner-coated

metal drums under nitrogen blanketing. This impermeable packaging under a modified atmosphere provides the primary protection against oxidation. Furthermore, the finished products are stored under refrigerated (2 to 8°C) or frozen (≤ -18°C) conditions.

Stability testing is ongoing and partial stability testing results can be found in Appendix B (results expected by March 2019). Based on analogous polyunsaturated fish oils or fish oil concentrates under similar storage conditions, the following storage conditions are recommended: 12 months under refrigerated conditions and 24 months under frozen conditions.

DHA Algal Powder(s)

Dry n-3® DHA as an example is a micro-encapsulated algal oil powder, high in polyunsaturated fatty acids and predominantly consisting of DHA. The product contains only traces of water (typically less than 3%). Due to the low water activity, the shelf life of the product is not limited by hydrolysis (increase in acid value) or microbial growth or spoilage. The shelf life of the product is only limited by oxidation. The dry algal oil powder is protected against oxidation by several means. Antioxidants such as tocopherol-rich extract and ascorbates are added during the manufacturing process. The encapsulation matrix consisting of milk protein, carbohydrates, and starch provide further protection against oxidation. Furthermore, the product is packed in aluminum-coated foil bags under nitrogen. This impermeable packaging under a modified atmosphere provides the primary protection against oxidation.

Based on stability data for one batch of this dry algal oil powder product and on the basis of stability testing of analogous polyunsaturated fish oils or fish oil concentrates under similar packaging conditions, a shelf life of 24 months at ≤25°C is recommended.

§ 170.235 Part 3, Dietary Exposure

Use in Foods

The proposed DHA algal oil and algal oil powder products are intended for use as direct food ingredients in foods to increase the dietary intake of the omega-3 fatty acid DHA. The approved use levels for menhaden fish oil (containing both DHA and EPA) in food is outlined in Table 9 as defined in 21 CFR § 184.1472, along with the proposed maximum use levels for the proposed DHA algal oil.

As noted for menhaden oil and other sources of DHA and/or EPA, FDA has determined that these oils may be used at a level providing a total intake of DHA and/or EPA up to 3.0 grams per day. A review of previous GRAS notifications indicates that suppliers of DHA and EPA products, as well as their GRAS expert panels, have generally recommended a maximum limit of 1.5 grams of DHA or EPA per day when combined together. The maximum levels of use were designed to assure that the combined daily intake of the two fatty acid components (i.e., EPA and DHA) would not exceed 3 grams per person per day. FDA has concurred with such an approach as they have provided "no questions" letters regarding such proposed food uses and associated intakes. In addition, the proposed food uses for BASF's DHA-rich algal oil and algal oil powder products are identical to the uses for other GRAS DHA and/or EPA products.

Therefore, in the event that a manufacturer blends BASF's DHA-rich algal oil with another oil that is a source of DHA and/or EPA, such a mixture would be appropriate (in meeting FDA's 3.0 gram per day limit as described above) provided that (1) the DHA-rich algal oil is used at a level that would not result in an exposure of more than 1.5 grams of DHA per day and (2) the other oil source of DHA and/or EPA is used at a level that would not result in a cumulative exposure of DHA and EPA greater than 3.0 grams per person per day. Since the proposed DHA algal oil contains approximately 40% DHA compared to about 20% combined DHA and EPA in menhaden oil, the use levels need to be reduced to 25% of the menhaden oil levels to account for the 50% percent use level for DHA only, and the difference in concentration of DHA in the proposed algal oil (approximately 40%) compared to the concentration of EPA and DHA in menhaden oil (20%). A similar adjustment would be made for the algal oil powder product that contains a lower concentration of DHA.

The European Union (EU) Commission has also recently amended the levels and conditions of use of the oil from the microalgae *Schizochitrium* sp. (Regulation (EU) 2018/1032). The Annex of the amendment described specified food categories and maximum use levels (mg/100 g for food, and mg DHA/day for dietary supplements) and is included here for reference (EU, 2018).

Table 9: Approved Use Levels of Menhaden Oil (DHA+EPA) Compared to Proposed Maximum Use Levels of BASF's DHA Algal Oil in Food

Category of food	Maximum approved level of menhaden oil in food (as served)[1]	Maximum intended use level of DHA Algal Oil in food (as served)[2]
Baked goods, baking mixes	5.0%	1.25%
Cereals	4.0%	1.00%
Cheese products	5.0%	1.25%
Chewing gum	3.0%	0.75%
Condiments	5.0%	1.25%
Confections	5.0%	1.25%
Dairy product analogs	5.0%	1.25%
Egg products	5.0%	1.25%
Fats, oils	12.0%	3.00%
Fish products	5.0%	1.25%
Frozen dairy desserts	5.0%	1.25%
Gelatins, puddings	1.0%	0.25%
Gravies, sauces	5.0%	1.25%
Hard candy	10.0%	2.50%
Jams, jellies	7.0%	1.75%
Meat products	5.0%	1.25%
Milk products	5.0%	1.25%
Nonalcoholic beverages	0.5%	0.125%
Nut products	5.0%	1.25%
Pastas	2.0%	0.50%
Plant protein products	5.0%	1.25%
Poultry products	3.0%	0.75%
Processed fruit juices	1.0%	0.25%
Processed vegetable juices	1.0%	0.25%
Snack foods	5.0%	1.25%
Soft candy	4.0%	1.00%
Soup mixes	3.0%	0.75%
Sugar substitutes	10.0%	2.50%
Sweet sauces, toppings, syrups	5.0%	1.25%
White granulated sugar	4.0%	1.00%

[1] Per 21 CFR § 184.1472

[2] Use levels reduced to 25% (DHA algal oil) of menhaden oil levels as described above

Use in Infant Formula

BASF does not manufacture infant formula, but only manufactures the DHA algal oil and encapsulated powder ingredients for use in food and infant formula. As such, they are an alternative source of DHA for incorporation in food, including infant formula. Therefore, BASF's DHA ingredients could be used in any exempt (pre-term or term) or non-exempt formula that contains DHA.

DHA algal oil and the encapsulated powder form are intended for use as direct ingredients in exempt (pre-term or term) and non-exempt (term) infant formula, in accordance with current good manufacturing practices (cGMP), and in combination with a source of arachidonic acid (ARA). The ratio of DHA to ARA would range from 1:1 to 1:2. The intended use level is similar to all other approved uses for incorporation of DHA in infant formula. As presented and discussed in previous GRAS submissions, it is assumed that infants consume about 100-120 kcal/kg bw/day, of which fat constitutes approximately 50% of calories, or approximately 5.5–6.7 g fat/kg bw/day (1 g of fat is equivalent to 9 kcal). Assuming incorporation of the proposed DHA ingredient at a maximum use level of 0.5% of total fat, the intake of DHA would be 27–33 mg/kg bw/day. This DHA intake estimate is in agreement with current recommendations for DHA consumption by pre-term and term infants of 18–60 mg/kg bw/day (Koletzko et al., 2014).

§ 170.240 Part 4, Self-Limiting Levels of Use

The use of DHA and DHA algal oil and powder in foods and infant formula is controlled as described in Part 3. As such, there are no self-limiting levels of use.

§ 170.245 Part 5, Experience Based on Common Use in Food

The statutory basis for our conclusion of GRAS status in the notice is not based on common use in food.

§ 170.250 Part 6, GRAS Narrative

History of Use/Regulatory Approval of DHA Algal Oil

DHA-rich oils from numerous sources including microalgae are considered GRAS for use in food for human consumption, including infant formula (FDA 2001; 2003a; 2003b; 2010, 2011a; 2011b; 2014a, 2014b, 2017, 2018a; 2018b). Two other GRAS notifications (GRNs 731, 732) for DHA-rich oils from microalgae are pending (FDA 2017a; 2017b). Global infant formula standards in the Food Chemicals Codex, as well as those in the EU, China, and Australia, allow the addition of DHA to infant formula as an optional ingredient (EU Commission, 2006; PRC, 2010; FSANZ, 2014; EU Commission, 2018). Sources of the oils include *Schizochytrium* sp., *Ulkenia* sp. SAM2179, *Chlorella protothecoides* strain S106, and *Prototheca moriformis* strain S2532. In addition, FDA has approved other sources of DHA for use in human food and/or infant formula, such as menhaden and fish oils (FDA, 2008a). Table 10 provides a list of a number of approvals of DHA from algal sources as well as marine sources for incorporation in pre-term and term infant formula.

Table 10. Regulatory approvals for use of DHA in infant formula

Year Approved	Country	Submission
2001	USA	GRN 41; DHASCO (docosahexaenoic acid-rich single-cell oil) from *Crypthecodinium cohnii* for use in infant formula
2006	USA	GRN 94; Docosahexaenoic acid-rich oil from tuna (DHA-rich tuna oil)
2011	USA	GRN 379; DHA from tuna oil
2015	EU/UK	DHASCO-B (docosahexaenoic acid-rich single-cell oil) from *Schizochytrium* sp. for use in infant formula
2015	USA	GRN 553; Algal oil (40% docosahexaenoic acid) derived from *Schizochytrium* sp.
2017	USA	GRN 677; Algal oil (40% docosahexaenoic acid) derived from *Schizochytrium* sp.
2018	USA	GRN 776; Algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. FCC-1324
2018	USA	GRN 777; Algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. FCC-3204
2018	EU	Oil from micro algae *Schizochytrium* sp. as a novel food for use in food including infant formula

As summarized above, DHA, produced via fermentation employing various microalgae, has previously been approved and sold for incorporation in infant formula. This includes approval of algal oil from *Schizochytrium* sp. The approvals authorized the addition of DHA at levels up to 0.5% of the total fatty acids in both exempt (pre-term and term) and non-exempt formulas.

In addition, DHA rich oils from microalgal sources including *Schizochytrium* sp. have been the subject of several authorization decisions and/or notifications under the European Union (EU) Novel Foods and Food Ingredients Regulation 258/97. The first such authorization was Commission Decision 2003/427/EC in June of 2003 which authorized the use of DHA-S oil from the thraustochytrid microalgae *Schizochytrium* sp. in a range of foodstuffs and established a specification for the material (OmegaTech, 2001). This was followed in December 2003 by a notification under Article 5 of the novel food regulation for placement on the market of a DHA-rich oil derived from a second thraustochytrid microalgae *Ulkenia* sp. on the grounds of its substantial equivalence with the oil from *Schizochytrium* sp (Schmitt et al, 2012a). To date, algal oil produced from *Schizochytrium* sp. (DHA-S) has been approved for direct use in foods by the U.S. Food and Drug Administration (FDA), Health Canada, European Union, Food Standards Agency of Australia, China's Ministry of Health, and Brazil's National Health Surveillance Agency (FDA, 2014a). Furthermore, a Novel Food Application was approved for the use of DHA-B in conventional foods, infant formula and follow-up formula, and food supplements (DSM, 2013; EU, 2015). In 2009, Commission Decisions 2009/777/EC and 2009/778/EC authorized extensions to the approved food uses of the oils from *Ulkenia* sp. and *Schizochytrium* sp., respectively. A third DHA-rich oil derived from the microalgae *Crypthecodinium cohnii* was already on the EU market before the Novel Food Regulation came into effect and was therefore legally in use without the need for explicit approval (Schmitt et al., 2012a). It should also be noted that in 2012, the UK Food Standards Agency concluded that T18 algal oil met the criteria for equivalence as defined in Article 3(4) of regulation (EC) 258/97 and that the *Schizochytrium* strain used in the production of T18 oil was substantially equivalent to other *Schizochytrium* sp. DHA-rich algal oils (Food Standards Agency, 2012). In 2018, Commission Decision 2018/1032 authorized the extension of the use of the oil from micro algae *Schizochytrium* sp. (EU Commission, 2018). In the U.S., the three DHA rich oils described above have also been the subjects of GRAS notifications (GRN Nos. 41, 137, 319) to which the FDA had no objections (FDA, 2000; 2003a; 2010).

Safety

Introduction

DHA is an important component of most cell membranes and tissues. DHA and DHA algal oils are currently marketed for use in food, dietary supplements, and infant formula for human consumption. The BASF DHA algal oil and powder products from *Schizochytrium* sp. T18 have a similar lipid (fatty acid) profile to that of currently marketed DHA from *Schizochytrium* sp. (FDA, 2016). Regulatory authorities have reviewed the safety of DHA and DHA algal oils and found their use to be safe in human food, including infant formula. Numerous studies and publications support the safety of

DHA and DHA algal oils, including *in vitro* studies, *in vivo* animal studies, and clinical studies in humans. A summary of the most relevant studies on DHA acute and subchronic toxicity, reproductive and developmental toxicity, mutagenicity and genotoxicity, chronic toxicity, carcinogenicity, and irritation/sensitization, along with clinical and epidemiological studies, have been summarized and reviewed (see Tables 11 and 12). Kroes et al. (2003) has reviewed/summarized the well-understood metabolic fate of dietary DHA, which is similar to other dietary fatty acids. The published data, as well as reviews conducted by regulatory authorities, support the conclusion that BASF's DHA-rich algal oil and powder products are safe for use in food and in exempt (pre-term and term) and non-exempt infant formulas.

Safety Data

Literature searches were performed to identify available safety data on DHA and DHA algal oil through July 2018 in both adult consumers as well as infants. This included searching sources of information such as publicly available assessments, databases, or reviews from organizations including the European Food Safety Authority (EFSA), Joint FAO/WHO Expert Committee on Food Additives (JECFA), U.S. FDA, and the World Health Organization (WHO), general Internet searching, as well as searching databases such as EMBASE, MEDLINE, TOXLINE, and PubMed.

Toxicological Studies

Animal Studies (with Schizochytrium sp. T18-derived algal oil)

Toxicity testing has been conducted with a proposed DHA-rich algal oil product from T18 (Schmitt et al., 2012a,b). Schmitt et al. (2012a) conducted a battery of *in vitro* and *in vivo* genotoxicity tests (microbial reverse mutation assay, *in vivo* rat bone marrow micronucleus assay, and chromosomal aberration assay in cultured human peripheral blood lymphocytes) with DHA-rich algal oil T18. The DHA-rich algal oil was not mutagenic or genotoxic in any of the assays. In addition, the acute oral LD_{50} in rats was estimated to be greater than 5000 mg/kg of body weight.

In addition, Schmitt et al. (2012a) administered DHA-rich algal oil at concentrations of 0, 10,000, 25,000, or 50,000 ppm in the diet to rats for 13 weeks. The algal oil was well-tolerated and there was an absence of toxicologically significant treatment-related effects on the general condition and appearance of the rats, neurobehavioral endpoints, growth, feed and water intake, ophthalmoscopic examinations, routine hematology and clinical chemistry parameters, urinalysis, and necropsy findings. The no-observed-adverse-effect level (NOAEL) was the highest dietary concentration level of 50,000 ppm, equivalent to 3,305 and 3,679 mg/kg bw/day for male and female rats, respectively. The study results confirmed that the DHA-rich algal oil T18 possessed a toxicity profile similar to other currently marketed algal oils and supported the safety of the proposed DHA-rich algal oil T18 for its proposed use in food.

Schmitt et al. (2012b) conducted both a developmental toxicity study and a 3-month dietary toxicity study with an *in utero* exposure phase of T18 in the rat. Based on the

absence of maternal and developmental toxicity at any dose level tested in the developmental toxicity study, the high-dose of 2000 mg/kg/day was considered the NOAEL for maternal toxicity and embryo/fetal development when DHA-rich algal oil was administered orally by gavage to pregnant Crl:CD(SD) rats during gestation days 6 - 19. In the 3-month dietary toxicity study with an *in utero* phase, the NOAEL for systemic toxicity for F_0 male and female rats and F_1 male rats was considered to be 50,000 ppm (highest concentration administered) and 25,000 ppm for F_1 female rats (based on higher mean body weight, body weight gain, and food consumption).

Mean body weight gain for the 50,000 ppm algal oil group females was similar to the DHA fish oil group during PND 21–35. However, slightly higher mean body weight gain was noted for females in this group beginning on PND 35 and generally continued throughout the remainder of the study; the difference was significant ($p < 0.05$) during PND 77–84 only. As a result, mean body weight gain in the 50,000 ppm algal oil group females was 32 g higher than the DHA fish oil group when the entire generation (PND 21–112) was evaluated and higher mean body weight during PND 70–112 (significant; $p < 0.05$ on PND 84 only). These increases were attributed to algal oil exposure. Mean food consumption in the 50,000 ppm algal oil group females was generally higher than the DHA fish oil throughout the entire generation (PND 21–112); the differences were often significant ($p < 0.05$ or $p < 0.01$). These increases corresponded to the effects on mean body weights observed in this group and therefore, were attributed to test article exposure.

The 50,000 ppm exposure level was equivalent to 3421 and 2339 mg/kg/day for F_0 males during pre-mating and after mating, respectively; 3558, 3117, and 7464 mg/kg/day for F_0 females during pre-mating, gestation, and lactation, respectively; and 3526 and 4138 mg/kg/day for F_1 males and females, respectively. Reproductive performance values, estrous cycle length, gestation length, process of parturition, and the numbers of former implantation sites and unaccounted-for sites for the F_0 generation were unaffected by algal oil exposure. F_1 generation postnatal survival and developmental parameters were unaffected by algal oil exposure at all dietary concentrations tested. There were no neurotoxic effects noted at any algal oil exposure level. The authors concluded that the results further supported the safety of DHA-rich algal oil T18 for its proposed use in food. The above studies are summarized in Table 11.

Table 11. Summary of preclinical toxicological study data on DHA-rich algal oil T18

Findings/Observations	Reference
Acute Toxicity	
Results: DHA-rich algal oil T18; oral LD_{50} in female Sprague-Dawley albino rats only, >5 g/kg.	Schmitt et al., 2012a
Subchronic Toxicity	
Study Design: Male and female Hsd:Sprague-Dawley SD rats were administered 0, 1, 2.5 or 5.0% DHA-rich algal oil T18 in the diet for 13 weeks. **Results:** NOAEL was the highest concentration tested (5% in the diet), equivalent to 3305 and 3679 mg/kg bw/day in male and female rats, respectively.	Schmitt et al., 2012a
Reproductive/Developmental Toxicity	
Study Design: DHA-rich algal oil T18 was tested for reproductive and developmental toxicity in Sprague-Dawley rats following oral gavage administration. **Results (Developmental/Maternal Toxicity):** The DHA algal oil (dosage levels of 400, 1000, and 2000 mg/kg/day) did not produce maternal and developmental toxicity at any dosage level. The high dosage level tested of 2000 mg/kg/day was considered to be the NOAEL for maternal toxicity and embryo/fetal development when DHA-rich algal oil was administered orally by gavage to pregnant Crl:CD(SD) rats during gestation days 6 - 19. **Results (Reproductive Toxicity):** In a 3-month dietary toxicity study with an *in utero* exposure phase in rats, the NOAEL for F0 male and female and F1 male systemic toxicity was considered to be 50,000 ppm (highest concentration administered) and 25,000 ppm for F1 female systemic toxicity (based on higher mean body weight, body weight gain, and food consumption). Reproductive performance values, estrous cycle length, gestation length, or the process of parturition, and the numbers of former implantation sites and unaccounted-for sites of the F0 generation were unaffected by algal oil exposure. F1 postnatal survival and developmental parameters were unaffected by algal oil exposure at all dietary concentrations. There were no neurotoxic effects noted at any DHA exposure level.	Schmitt et al., 2012b
Genotoxicity/Mutagenicity	
Study Designs: DHA-rich algal oil T18 was tested in a battery of *in vitro* and *in vivo* genotoxicity tests (microbial reverse mutation assays, rat bone marrow micronucleus assay, chromosomal aberration assay in human peripheral blood lymphocytes). **Results:** In all assays, the DHA algal oil did not demonstrate mutagenic or genotoxic potential.	Schmitt et al., 2012a

Animal Studies (with other DHA algal oil products)

Numerous studies have been conducted with other DHA algal oils and fish oils, including acute toxicity studies (FDA, 2010), subchronic studies (Fedorova-Dahms et al., 2011; Hammond et al., 2001a; Boswell et al., 1996; Wilbert et al., 1997; Arterburn et al. 2000a; Burns et al., 1999; Blum et al., 2007a; Kroes et al., 2003; Lewis et al., 2016), reproductive and developmental toxicity studies (Hammond et al., 2001b,c; Arterburn et al. 2000b; Kroes et al., 2003; Blum et al., 2007b; Falk et al., 2017), genotoxicity and mutagenicity studies (Kroes et al., 2003; Hammond et al., 2002; Arterburn et al., 2000c; Fedorova-Dahms et al., 2011; Blum et al., 2007a), and other safety-related studies (Fedorova-Dahms et al., 2014; Huang et al., 2002; Abril et al., 2003; Turk et al., 2013; Huang et al., 2015; IOM, 2005). No toxicologically significant treatment-related effects were observed in these studies as summarized in Table 12. Only published studies are referenced, although numerous unpublished studies have also been referenced in previous GRAS notifications and support the safety of DHA algal oils. In addition, numerous safety studies of a dried algal biomass were conducted (i.e., *in vitro* and *in vivo* genetic toxicity, subchronic toxicity in rats, reproductive and developmental toxicity in rats and/or rabbits), also without notable toxicity (GRN 553; FDA, 2014a).

The FDA has reviewed the safety information submitted as a part of GRNs for these DHA oil products (e.g., DHASCO-B (FDA, 2000, 2014a); DHA-45 oil (Lonza; FDA, 2010), fish/anchovy oil (FDA, 2003b)). As one example, several published studies were submitted as part of GRN 319 (FDA, 2010) for a DHA algal oil derived from *Ulkenia* sp. SAM2179. Based on the entirety of the regulatory and safety information/data provided, FDA issued a "no questions letter" regarding the proposed use of DHA algal oil (*Ulkenia* sp. SAM 2179) in food. Similar safety studies and resultant FDA "no questions letters" have also been issued for other DHA sources (e.g., fish oils) and GRAS notifications as described in the History of Use section (Part 6).

Table 12. Summary of preclinical toxicological study data on other DHA and DHA algal or fish oil products

Findings/Observations	Reference
Acute Toxicity	
Results: *Ulkenia* DHA oil (45% DHA from *Ulkenia* sp. algae); oral LD_{50} in male ICR mice and male and female Sprague-Dawley (Crj/CD(SD)IGS) rats reported to be >2 g/kg.	FDA, 2010
Subchronic Toxicity	
Study Design: DHA-rich algal oil from *Schizochytrium* sp., containing 40 - 45 wt% DHA and up to 10 wt% EPA, was evaluated in a subchronic (90-day) dietary study in male and female Sprague–Dawley rats with an *in utero* exposure, followed by a 4-week recovery phase. DHA-rich algal oil dietary levels of 0.5, 1.5, or 5 wt% along with two control diets (a standard low-fat basal diet and a basal diet supplemented with 5 wt% of concentrated fish oil) were administered. **Results:** No treatment-related effects were noted in clinical observations, body weight, food consumption, behavior, hematology, clinical chemistry, coagulation, or urinalysis. Increases in absolute and relative weights of the liver, kidney, spleen and adrenals (adrenals and spleen with histological correlates) were observed in both the fish oil- and the high-dose of DHA-rich algal oil-treated females but were not considered to be adverse by the authors. The NOAEL for DHA-rich algal oil was the highest dose tested (5% in the diet), equivalent to DHA algal oil intakes of 4122 and 4399 mg/kg bw/day for male and female rats, respectively.	Fedorova-Dahms et al., 2011
Study Design: DHA-rich algal oil from *Schizochytrium* sp. (fermentation biomass) was administered in the diet of male and female Sprague-Dawley Crl:CD(SD)BR rats at doses of 110 to 1090 mg DHA/kg bw/day for 13 weeks. **Results:** No treatment-related adverse effects were noted at any dose.	Hammond et al., 2001a
Study Design: DHA-rich oil from *C. cohnii* was administered to male and female Sprague-Dawley rats both orally by gavage and in the diet in two separate 4-week toxicity studies. Doses ranged from 25 to 1250 mg/kg bw/day by gavage and 210 to 1180 mg/kg bw/day in the diet. **Results:** No treatment-related adverse effects were noted. Periportal hepatocellular vacuolation was noted in female rats but was considered related to the consumption of diets high in fat. The highest doses administered (1250 and 1180 mg/kg/day) were considered the NOAELs.	Boswell et al., 1996; Wilbert et al., 1997
Study Design: DHA-rich oil from *C. cohnii* was administered by oral gavage to male and female Sprague-Dawley rats for 13 weeks. Doses ranged from 500 to 1250 mg/kg bw/day. **Results:** No treatment-related adverse effects were observed.	Arterburn et al. 2000a

Findings/Observations	Reference
Study Design: DHA-rich oil (DHA-Arachidonic Acid (ARA) blend) from *C. cohnii* was administered in the diet to male and female Sprague-Dawley rats for 13 weeks (including an *in utero* phase). Doses ranged from 410 to 3290 mg/kg bw/day. **Results:** The DHA oil did not produce treatment-related adverse effects in rats when administered for 13 weeks (including an *in utero* phase).	Burns et al., 1999
Study Design: DHA-rich oil (from *Ulkenia* sp. algae) was administered to male and female Sprague-Dawley Crj:CD(SD)IGS rats by gavage for 13 weeks. Doses ranged from 540 to 900 mg DHA/kg bw/day. **Results:** No treatment-related adverse effects were noted in clinical observations, food and water consumption, mortality, gross pathology, and histopathology. Increased body weights and liver weights in DHA oil-treated groups were observed. The changes were considered related to be physiologically adaptive to the large lipid load administered, and thus not regarded as toxicologically significant.	Blum et al., 2007a; Kroes et al., 2003
Study Design: DHA-rich oil (from *Schizochytrium* sp. algae) and arachidonic acid (ARA)-rich oil (from *Mortierella alpina*) were administered separately to male and female Wistar rats in the diet for 4 and 13 weeks. Doses ranged from 1000 to 5000 mg DHA or ARA oil/kg bw/day. Water or corn oil (vehicle control) rats served as the controls. **Results:** No treatment-related adverse effects were noted in clinical observations, body weight, food and water consumption, mortality, hematology, clinical chemistry, urinalysis, gross pathology, and histopathology. Observed increases in cholesterol and triglyceride levels were considered related to the oil-rich diets and not related to DHA or ARA. The NOAELs for DHA and ARA in both studies were 5000 mg/kg bw/day.	Lewis et al., 2016
Reproductive/Developmental Toxicity	
Study Design: In a single-generation reproduction toxicity study, DHA-rich algal oil from *Schizochytrium* sp. (fermentation biomass) was administered in the diet of male and female Sprague-Dawley rats at doses ranging from 130 to 5625 mg DHA/kg bw/day for 13 weeks. **Results:** No treatment-related adverse effects were noted in reproductive parameters (e.g., in estrus cycle duration, fertility, gestation length, pups per litter).	Hammond et al., 2001b

Findings/Observations	Reference
Study Designs: In two developmental toxicity studies conducted in female Sprague-Dawley rats and New Zealand White rabbits, DHA-rich algal oil from *Schizochytrium* sp. (fermentation biomass) was administered during gestation to rats (gestation days 6-15) via the diet and by oral gavage to rabbits (gestation days 6-19). Doses ranged from 130 to 5900 mg DHA/kg bw/day (rats) or 49 to 490 mg DHA/kg bw/day (rabbits). **Results:** No maternal or developmental toxicity was observed (e.g., no adverse effects on reproductive performance, postnatal survival) in rats. In rabbits, the high-dose DHA oil and fish oil treatment groups demonstrated reduced food consumption and body weight gain, and a slight increase in abortions when compared to the control group. However, the authors considered the effects to be related to the consumption of high-fat diets. No effects were noted in offspring in either study.	Hammond et al., 2001c
Study Design: In a developmental toxicity study, DHA-rich oil from *C.cohnii* was administered by oral gavage to pregnant Sprague-Dawley rats during days 6-15 of gestation, at doses ranging from 260 to 645 mg/kg bw/day. **Results:** No maternal/developmental toxicity was noted.	Arterburn et al. 2000b
Study Design: In a single-generation reproduction toxicity study, DHA-rich algal oil from *Ulkenia* sp. was administered by oral gavage to male and female Sprague-Dawley rats at doses ranging from 360 to 5040 mg DHA/kg bw/day. **Results:** No treatment-related adverse effects were noted on parameters of reproduction (e.g., estrus cycle duration, fertility, gestation length, pups per litter).	Kroes et al., 2003; Blum et al., 2007b
Study Designs: In a developmental and reproduction study in Wistar rats, DHA-rich oil (from *Schizochytrium* sp. algae) or arachidonic acid (ARA)-rich oil (from *Mortierella alpina*) was administered to male and female Wistar rats. Doses in the developmental study were administered to pregnant rats by oral gavage from gestation days 6 through 20 and included an untreated control group. Dosing in the reproduction study was via gavage pre-mating and throughout the mating period, pregnancy, and nursing/lactation period and included a corn oil (vehicle) control group. In both studies, doses ranged from 1000 to 5000 mg DHA or ARA oil/kg bw/day. **Results:** In the developmental study, no maternal or developmental toxicity was observed (e.g., no adverse effects on reproductive performance, postnatal survival) in rats. In the reproduction study, no treatment-related adverse effects were noted on parameters of reproduction (e.g., estrus cycle duration, fertility indices, gestation length, pups per litter). The NOAELs for DHA and ARA in both studies were 5000 mg/kg bw/day.	Falk et al., 2017
Genotoxicity/Mutagenicity	

Findings/Observations	Reference
Study Designs: DHA45-oil was evaluated in several *in vitro* genetic toxicity assays. Fujii and Suwa (1998a (unpublished), as cited in Kroes et al., 2003) investigated the potential mutagenicity of DHA45-oil in the Ames assay using *Salmonella typhimurium* strains TA97, TA98, TA100, and TA102 at concentrations of 0.5 - 5 mg DHA45-oil/plate, in the presence and absence of S9 fraction from the livers of Aroclor-induced rats. Bruijntjes-Rozier and van Ommen (2001 (unpublished), as cited in Kroes et al., 2003) evaluated the potential mutagenicity of DHA45-oil in *S. typhimurium* strains TA98, TA100, TA1535, and TA1537 and in *Escherichia coli* WP2 uvrA at concentrations of 0.06 - 5 mg DHA45-oil/plate, with and without metabolic activation. The ability of DHA45-oil to induce chromosomal aberrations was evaluated using Chinese hamster fibroblast cells, with and without metabolic activation (Kashima and Sarwar, 2000, (unpublished), as cited in Kroes et al., 2003). **Results:** No evidence of mutagenicity was detected in any of the *in vitro* studies. DHA45-oil also did not induce chromosome aberrations under the conditions of the study.	Kroes et al., 2003
Study Designs: Numerous *in vitro* assays were conducted with and without mammalian metabolic activation. **Results:** DHA-rich microalgae were not mutagenic in the Ames reverse mutation assay employing five different *Salmonella* strains. Similarly, DHA-rich microalgae was tested and found not to be mutagenic in the CHO AS52/XPRT gene mutation assay. It was not clastogenic to human peripheral blood lymphocytes in culture and did not induce micronucleus formation in mouse bone marrow in *vivo*.	Hammond et al., 2002
Study Designs: Docosahexaenoic acid single cell oil (DHASCO), a microbially-derived triglyceride rich in docosahexaenoic acid was tested for mutagenic activity in three different *in vitro* mutagenesis assays. All assays were conducted with and without metabolic activation. **Results:** DHASCO oil was not mutagenic in the Ames reverse mutation assay using five different *Salmonella* tester strains, nor was DHASCO mutagenic in the mouse lymphoma TK(+/-) forward mutation assay. The oil also was not clastogenic in a chromosomal aberration assay performed with Chinese hamster ovary cells.	Arterburn et al., 2000c
Study Designs: DHASCO-B oil was tested in the Ames reverse mutation assay, in an *in vitro* mammalian chromosome aberration test in human lymphocytes, and in an *in vivo* mouse micronucleus study in immature erythrocytes of the bone marrow. **Results:** DHASCO-B oil was found to be non-mutagenic/non-genotoxic.	Fedorova-Dahms et al., 2011
Design/Results: DHA-algal oil (*Ulkenia* sp.) was non-mutagenic in various bacterial strains (Ames assay) and did not induce chromosomal aberrations in Chinese hamster fibroblast cells.	Blum et al., 2007a

Findings/Observations	Reference
Study Designs: DHA algal oil (*Schizochytrium* sp.) was tested in the Ames reverse mutation assay, in an *in vitro* mammalian chromosome aberration test in human lymphocytes, and in an *in vivo* erythrocyte micronucleus study in polychromatic erythrocytes of the bone marrow of Wistar rats. **Results:** The DHA algal oil was found to be non-mutagenic/non-genotoxic.	Lewis et al., 2016
Additional Safety-Related Studies	
Study Design: Bioequivalence study in domestic Yorkshire Crossbred neonatal pigs. Diets containing DHASCO-B or DHASCO blended with ARASCO (ARA single cell oil) were administered from day 2 to 22 after birth. **Results:** Both diets were well-tolerated and diets were found to be bioequivalent.	Fedorova-Dahms et al., 2014
Study Design: The effect of administration of DHA to female pigs/piglets was measured by changes in clinical chemistry and organ weights. Four bovine-milk-based formulas with AA/DHA=0, 34/17, 68/34 and 170/85 (mg per 100 kcal formula) were administered for a period of 30 days. **Results:** No treatment-related differences between groups of piglets receiving DHA and control diets were noted.	Huang et al., 2002
Study Design: Male early-weaned pigs were fed the fermentation biomass of the DHA-producing organism *Schizochytrium* sp for 120 days. DHA-rich microalgae (DRM) was incorporated into the diet of the first treatment group at a level delivering 2.680 kg DRM per pig over the course of 120 days (a constant, whole-life exposure) equating to 598 g DHA per pig. DRM was incorporated into finisher diets only (administered over the last 42 days of the growing cycle) to treatment groups 2, 3, and 4 delivering 1.169, 3.391, and 5.746 kg DRM per pig (261, 756, and 1281 g DHA per pig). These levels represented approximately 1, 3, and 5 times the anticipated commercial dose and were delivered in a feeding strategy designed to mimic commercial use. **Results:** No effects were noted in hematology parameters, organ weights, or histopathology (liver, heart, and spleen) compared to animals receiving control diets. No attempt was made to balance fat between the control and treatment group diets in the study.	Abril et al., 2003
Study Design: A mouse immortalized colonocyte model study was conducted. Mice were fed either a corn oil-, DHA-, or EPA-enriched diet prior to intestinal wounding (2.5% dextran sodium sulfate for 5 days followed by termination after 0, 3, or 6 days of recovery). Diet composition (g/kg diet) was as follows: 440 sucrose, 200 casein, 220 cornstarch, 3 DL-methionine, 35 AIN-76 salt mix, 10 AIN-76 mineral mix, 2 choline chloride, and 60 cellulose (Bio-Serv) + 30 CO (CO diet), 10 DHA & 20 CO (DHA diet), or 10 EPA + 20 CO (EPA diet). Diets were replaced daily. Animals were fed the experimental diets for 10 days. **Results:** DHA uniquely reduced epidermal growth factor receptor (EGFR) ligand-induced receptor activation (wound healing events), whereas DHA and its metabolic precursor EPA reduced wound-induced EGFR transactivation compared with the control group (no fatty acid or linoleic acid). The results indicate that, during the early response to intestinal wounding in this mouse colonocyte model, DHA and EPA delay the activation of key wound-healing processes in the colon.	Turk et al., 2013

Findings/Observations	Reference
Study Design: A proteomics study was conducted in apoE-knockout mice to provide insights into PUFA-regulated hepatic protein. The control group was given normal laboratory mouse diet ad libitum and 1.1% ethanol in phosphate buffered saline (PBS) (150 mM NaCl, 20 mM sodium phosphate, pH 7.4) by gavage every day for 10 weeks. Similarly, the four test groups were fed the same normal diet ad libitum plus 200 mg/kg bw/day of DHA, EPA, ARA, or linoleic acid in 1.1% ethanol/PBS every day by gavage for 10 weeks. In addition, incubations of Hep G2 cells with n-3PUFUs assessed potential molecular mechanisms by which PUFAs influenced responses of inflammatory mediators to cytokine challenge. **Results:** The in vivo proteomic study revealed PUFAs both upregulate and down regulate expression of proteins related to oxidative stress and the inflammatory cascade, thus suggesting they may act as either pro-inflammatory or anti-inflammatory agents. Cytokine-challenged HepG2 cells were used to reveal the anti-inflammatory function of n-3 PUFAs. The results showed that interleukin (IL)-1β combined with IL-6 induced C-reactive protein (CRP) mRNA expression and its protein secretion by HepG2 cells. The CRP promoter activity was significantly increased in the IL-6-treated cells, whereas IL-1β alone had no effect. However, IL-1β and IL-6 acted synergistically to further enhance CRP promoter activities. n-3 PUFAs inhibited nuclear factor-κ B (NF-κ B) activation and the phosphorylation of the nuclear signal transducer and activator of transcription 3 (STAT3) during cytokine-induced CRP production. The results of this study indicate that PUFAs induce changes in the hepatic protein profile in vivo. Furthermore, n-3 PUFAs exert their anti-inflammatory properties through differential molecular mechanisms in hepatic cells. The authors stated that "that further research is needed to extend our knowledge of PUFA physiological functions".	Huang et al., 2015
Review	
IOM reviewed studies of DHA and noted that DHA administration to animals via the diet has produced an increase in lipid peroxidation and oxidative damage in erythrocytes, liver, and kidney membranes, and bone marrow DNA. However, IOM noted that the effects were reduced or mitigated with co-administration of vitamin E (Ando et al., 1998; Song and Miyazawa, 2001; Umegaki et al., 2001; Yasuda et al., 1999; Leibovitz et al., 1990 as cited by IOM, 2005).	IOM, 2005

Human Studies - Adults

Adverse effects observed in human studies involving very high doses of n-3 fatty acids have included bleeding complications, impaired immune function, increased lipid peroxidation, increased LDL-cholesterol, impaired lipid and glucose metabolism, and gastrointestinal (GI) disturbances (EFSA, 2012). However, it was noted that the reported oxidative damage seemed to be associated with very high doses of DHA and EPA, and products that were not supplemented with vitamin E (EFSA, 2012).

Kroes et al. (2003) reviewed clinical studies related to the safety of DHA oils and described numerous clinical trials of 1 week to 1+ years in length. The authors indicated

that the clinical trials reported that DHA (at intakes up to 6 g DHA/person/day) in fish or marine-derived oils, alone or in combination with EPA and/or DPA, did not produce adverse effects on identified parameters of interest such as LDL cholesterol levels, glycemic control, bleeding time, platelet aggregation, and/or other hemostatic parameters.

An EFSA expert panel published a scientific opinion paper on the tolerable upper intake level (UL) of the LCPUFAs, EPA, DHA, and docosapentaenoic acid (DPA) (EFSA, 2012). The EFSA Panel considered the adverse effects in humans described above, following high intakes of DHA and EPA. Long-term intervention studies that evaluated the effects of supplemental intakes of EPA and DHA, either alone or in combination, at doses of up to about 1 g/day on a variety of health outcomes (e.g., cardiovascular, neurological, immunological) were reviewed. The EFSA Panel stated that the clinical studies generally reported no adverse effects related to the consumption of DHA or EPA at these doses (i.e., either alone or in combination, up to about 1 g/day). They also concluded that long-term supplemental intakes of DHA and EPA (combined up to about 5 g/day) do not increase the risk of spontaneous bleeding episodes or bleeding complications even in subjects at high-risk for bleeding (e.g. taking acetylsalicylic acid or anti-coagulants). The Panel (EFSA, 2012) concluded that supplemental intakes of EPA and DHA combined at doses up to 5 g/day, and supplemental intakes of EPA alone up to 1.8 g/day, do not raise safety concerns for the adult population.

Additional conclusions of the EFSA Panel (2012) regarding DHA/EPA supplementation and health/safety outcomes included the following:

- Supplemental intakes of DHA and EPA (combined at doses of up to 5 g/day) for up to 12 weeks do not significantly affect glucose homeostasis in healthy or diabetic subjects. They also do not induce changes in immune functions that could raise concerns related to the risk of infections or inappropriate activation of inflammatory responses.

- Consumed alone or in combination at doses up to 5 g/day for up to 16 weeks, supplemental intakes of DHA and EPA do not induce changes in lipid peroxidation.

- Supplemental intakes of DHA and EPA (combined doses of up to 2 - 6 g/day) and supplemental intakes of mostly DHA (2 - 4 g/day) increase blood concentrations of LDL cholesterol by about 3%. The increase is accompanied by a decrease in triglycerides with no changes in total (or non-high density lipoprotein (HDL) cholesterol concentrations. The panel concluded that the minimal increase in LDL-cholesterol concentrations of 3% associated with combined DHA and EPA supplementation or with DHA supplementation alone, at the doses referenced above, does not have an adverse effect on cardiovascular disease risk.

- Consumption of n-3 LCPUFA (including DHA and/or EPA) at observed intake levels has not been associated with adverse effects in healthy children or adults.

Numerous scientific and regulatory authorities such as the German Federal Risk Assessment Agency (BfR), Norwegian Scientific Committee for Food Safety (VKM), and the U.S. Institute of Medicine (IOM) have also evaluated the available long-term human intervention studies and published scientific opinions related to possible adverse effects and health outcomes related to consumption of DHA and/or EPA (EFSA, 2012; VKM, 2011; IOM, 2005) and came to similar conclusions as that of the EFSA review panel (2012). The EFSA panel (2012) considered and referenced all the data/opinions of all these authorities as part of their review.

Human Studies - Infants

Numerous algal and marine sources of DHA have been evaluated by the FDA and other global regulatory agencies over the past 15 years for proposed incorporation in food for human consumption, including infant formula. Relevant US GRAS notifications include GRN 41, GRN 94, GRN 379, GRN 553, GRN 677, GRN 731, GRN 776, and GRN 777 (FDA, 2000, 2001, 2011a, 2014a, 2016, 2017a, 2018a, 2018b). All of the GRAS notices provided information/clinical study data that supported the safety of the proposed DHA ingredients for use in infant formula. In all of the studies summarized in these notifications, there were no significant adverse effects/events or tolerance issues in infants attributable to DHA-supplemented formulas when compared to control-group infant formulas. The studies reviewed in these notifications supported the safe use of DHA in infant formula up to 1% of total fatty acids.

A review of data published since 2017 conducted as part of this GRAS notification supports the summaries provided in previous GRAS notifications. Studies of DHA in infant formulas at concentrations up to 1% did not report serious adverse effects and very often concluded that the addition of DHA to infant formula resulted in benefits to growth and development. While some studies report minor gastrointestinal effects, such as increased gas in infants using DHA-supplemented formula, a review conducted by FDA (2008b) demonstrates that these effects do not warrant concern; therefore, they are not discussed in detail in this notification. In response to a petition, FDA analyzed reported adverse events in the CFSAN Adverse Event Reporting System (CAERS) database for formulas containing DHA oils from 2000 to 2009 (FDA, 2008b). Following their review, FDA concluded that there were no statistically significant increases in the proportion of reported GI adverse events in infants receiving DHA-supplemented formulas over the time during which the market percentage of infant formulas containing algal oils went from 0% to 98%.

GRNs 379, 553, and 677 provided comprehensive summaries of the clinical study literature regarding DHA or long-chain polyunsaturated fatty acids (LCPUFA) relevant to supplementation of infant formula from fish and algal oil sources (FDA, 2011a, 2014a, 2017). Therefore, this notification includes only summaries of clinical studies published since the most recent GRN on the supplementation (stand alone or in infant formula) with DHA and/or DHA and ARA for use in exempt (preterm or term) or non-exempt infant formulas. A comprehensive literature search for clinical trials evaluating DHA in infant formula (published 2017–present) was performed, and titles and abstracts were reviewed.

Only those studies measuring the effects of supplemental DHA on relevant measures of morbidity, growth/development, and metabolism were considered for inclusion. Approximately ten published clinical trials were identified as meeting these criteria. Given the lack of reported serious adverse events, the clinical studies summarized below were selected to provide a representation of the beneficial effects of DHA supplementation.

Fetal and Childhood Growth

Colombo et al. (2017) reported on the DHA Intake and Measurement of Neural Development (DIAMOND) trial which studied the long-term dose-response effects of LCPUFA-supplemented formula feeding during infancy. The trial contrasted the effects of four formulations: 0.00% docosahexaenoic acid (DHA)/0.00% arachidonic acid (ARA), 0.32% DHA/0.64% ARA, 0.64% DHA/0.64% ARA, and 0.96% DHA/0.64% ARA against a control condition (0.00% DHA/0.00% ARA). The results of this trial show improved cognitive outcomes for infants fed supplemented formulas, but a common finding among many of the outcomes show a reduction of benefit for the highest DHA dose (i.e., 0.96%DHA/0.64% ARA, that is, a DHA:ARA ratio 1.5:1.0). The authors present, for the first time, data from infants' red blood cell (RBC) assays taken at 4 and 12 months of age. Those assays indicate that blood DHA levels generally rose with increased DHA supplementation, although those levels tended to plateau as the DHA-supplemented level exceeded 0.64%. Perhaps more importantly, ARA levels showed a strong inverted-U function in response to increased DHA supplementation; indeed, infants assigned to the formula with the highest dose of DHA (and highest DHA/ARA ratio) showed a reduction in blood ARA relative to more intermediate DHA doses. This finding raises the possibility that reduced ARA may be responsible for the reduction in benefit on cognitive outcomes seen at this dose. The findings implicate the DHA/ARA balance as an important variable in the contribution of LCPUFAs to cognitive and behavioral development in infancy.

Devlin et al. (2017) conducted a longitudinal, double blind, controlled trial in toddlers randomized to receive a DHA (200 mg/day) and ARA (200 mg/day) supplement or a corn oil supplement (control) until age 24 months and determined their effects on neurodevelopment. There was no effect of supplementation on the Bayley Scales of Infant and Toddler Development 3rd Edition (Bayley-III) cognitive and language composites and Beery-Buktenica Developmental Test of Visual-Motor Integration (Beery VMI) at age 24 months. Supplemented toddlers had higher RBC phosphatidylcholine (PC), phosphatidylethanolamine (PE), and plasma DHA and ARA compared to placebo toddlers at age 24 months. A positive relationship between red blood cell PE ARA and Bayley III Cognitive composite (4.55 (0.21-9.00), $p = 0.045$) in supplemented boys, but not in control boys, was observed in models adjusted for baseline fatty acid, maternal non-verbal intelligence, and BMI z-score at age 24 months. A similar positive relationship between red blood cell PE ARA and Bayley III Language composite was observed for supplemented boys (11.52 (5.10-17.94), $p = 0.001$) and girls (11.19 (4.69-

17.68), p = 0.001). The authors concluded that the findings suggest that increasing the ARA status in toddlers is associated with better neurodevelopment at age 24 months.

Rigo et al. (2017) assessed the growth and nutritional biomarkers of preterm infants fed human milk (HM) supplemented with a powdered HM fortifier (nHMF) or a control HM fortifier (cHMF). The nHMF provides similar energy content, 16% more protein (partially hydrolyzed whey), and higher micronutrient levels than the cHMF, along with medium-chain triglycerides and docosahexaenoic acid. A controlled, multicenter, double-blind study was conducted in preterm infants less than 32 weeks of age or less than 1500 g for a minimum of 21 days. Weight gain was evaluated for noninferiority (margin = -1 g/day) and superiority (margin = 0 g/day). Nutritional status and gut inflammation were assessed by blood, urine, and fecal biochemistries. Adverse events were monitored. The adjusted mean weight gain (analysis of covariance) was 2.3 g/day greater in nHMF versus cHMF; the lower limit of the 95% CI (0.4 g/day) exceeded both noninferiority (P < 0.001) and superiority margins (P = 0.01). Weight gain rate (unadjusted) increased when compared to the control group between study days 1 and 21. Length and head circumference (HC) gains between day 1 and day 21 were not different. Both HMFs were well tolerated with similar incidence of gastrointestinal adverse events. The authors concluded that the nHMF test article provided more protein and fat compared to a control fortifier and was safe, well-tolerated, and improved the weight gain of preterm infants.

Morbidity: Retinopathy of Prematurity

Retinopathy of prematurity (ROP) in extremely preterm infants can cause visual morbidity. Bernabe-Garcia et al. (2017) evaluated the effect of enteral DHA on development of retinopathy (ROP) of prematurity and its severity during the hospital stay of preterm infants. A double-blind, clinical trial was conducted in pre-term neonates with birth weights between 1000 – 1500 g. The DHA group received 75 mg of DHA/kg/day (Life's DHA, Martek Life Enriched®) and the control group received sunflower oil for 14 days by enteral feeding. Interim analyses were conducted to evaluate the effect on ROP incidence and severity. There were no differences between groups in total ROP incidence (36% vs. 42%, p = 0.333) nor its Relative Risk (RR). Likewise, on severe ROP incidence (81% vs. 58%, p= 0.132) or its RR= 0.445 (95% IC 0.141-1.404). However, a group showed a borderline reduction in the probability of severe ROP after adjustment for NSAIDs, steroids, gestational age at birth, duration with tissue saturation higher than 95%, events of apnea, tissue DHA content in erythrocytes and presence of respiratory distress syndrome. The authors concluded that the preliminary results suggest that enteral DHA at dose of 75 mg/kg/day might have a prophylactic effect on the incidence of severe ROP.

Neurodevelopment

Several recent clinical trials have demonstrated a benefit to neurodevelopmental parameters with DHA-supplemented infant formula (Andrew et al., 2017; Keim et al., 2018). Supplementation with DHA in term infants appeared to improve cognitive function.

Andrew et al. (2018) investigated whether DHA, choline, and uridine-5-monophosphate (UMP) supplementation improved neurodevelopmental outcome in infants with suspected cerebral palsy (CP) versus a comparison group of children. Infants aged 1 to 18 months with suspected CP were recruited from child development centers. Participants received daily treatment or control supplementation for 2 years in a double-blind, randomized control design. Stratification was by age, sex, predominant pattern of motor involvement (four limbs or other), and visual impairment (or not). The primary outcome was the cognitive composite score of the Bayley Scales of Infant and Toddler Development (CCS-Bayley-III). Secondary outcomes included language composite and motor composite scores of the Bayley Scales of Infant and Toddler Development. Forty infants were recruited; 35 began supplementation, 29 completed 1 to 2 years of supplementation. No statistically significant differences in neurodevelopmental outcome between the treatment and comparison groups were identified. Further investigation of neurodevelopmental outcome after supplementation with DHA, choline, and UMP of infants with suspected CP is warranted. This was the first trial of phosphatidylcholine precursor supplementation in infants with suspected cerebral palsy (CP). While there was no statistically significant neurodevelopmental advantage for the treatment group versus the comparison group, the treatment group cognitive and language advantage were clinically meaningful.

Keim et al. (2018) conducted a pilot Preemie Tots Trial to confirm the feasibility of a full-scale trial in toddlers born very preterm and exhibiting autism spectrum disorder (ASD) symptoms and to explore the effects of supplementation on parent-reported ASD symptoms and related behaviors. A 90-day, randomized, fully blinded, placebo-controlled trial in 31 children, 18-38 months of age, who were born at less than 29 weeks of gestation was conducted. One group was assigned to daily Omega-3-6-9 Junior (Nordic Naturals, Inc.) treatment (including 338 mg eicosapentaenoic acid, 225 mg DHA, and 83 mg GLA), and the other group received canola oil (124 mg palmitic acid, 39 mg stearic acid, 513 mg linoleic acid, 225 mg alpha-linolenic acid, and 1346 mg oleic acid). Mixed-effects regression analyses followed intent-to-treat analysis and explored effects on parent-reported ASD symptoms and related behaviors. Of 31 children randomly assigned, 28 had complete outcome data. After accounting for baseline scores, those assigned to the treatment group exhibited a greater reduction in ASD symptoms per the Brief Infant Toddler Social Emotional Assessment ASD scale than did those assigned to placebo (difference in change = - 2.1 points; 95% CI: - 4.1, - 0.2 points; standardized effect size = - 0.71). No other outcome measure reflected a similar magnitude or a significant effect. The authors concluded that the pilot trial confirmed adequate numbers of children enrolled and participated fully in the trial. No safety concerns were noted. It also found clinically-significant improvements in ASD symptoms for children randomly assigned to receive Omega-3-6-9 Junior, but effects were confined to one subscale. The authors proposed that a future full-scale trial is warranted given the lack of effective treatments for the target population.

Safety Data Summary

DHA and DHA algal oils are currently marketed for use in food, infant formula, and dietary supplements for human consumption. The DHA algal oil and powder from *Schizochytrium* sp. T18 has a similar proximate composition and lipid (fatty acid and sterol) profile to that of currently approved/marketed DHA oils from *Schizochytrium* sp. and other algal and marine sources. Regulatory authorities have reviewed the extensive safety study database of DHA and DHA algal oils and found their use to be safe for use in human food and infant formula. Numerous studies have been conducted and published in support of the evaluation of the safety of DHA and DHA algal oils, including *in vitro* studies, *in vivo* animal studies, and clinical studies in humans including infants. The most relevant studies on DHA acute and subchronic toxicity, reproductive and developmental toxicity, and mutagenicity and genotoxicity, along with clinical and epidemiological studies have been reviewed/summarized above.

In summary, the available published scientific data on the safety of DHA from algae and other sources (e.g., fish oil) including the *Schizochytrium* sp. algal source are extensive. The compositional profile of the DHA-rich algal oil and powder ingredients presents no obvious safety concerns. The totality of published study data, as presented in previous GRNs, reviewed by FDA (2008b), and summarized here, support the safe use of BASF's DHA algal foil and algal oil powder from *Schizochytrium* sp. in 1) foods and 2) in infant formulas up to 1% of total fatty acids. Additionally, FDA has already reviewed numerous GRAS notifications for similar products and their use in foods and infant formulas and issued "no questions" letters in those previous cases. Lastly, DHA products have been reviewed and approved around the world for addition to food, including infant formula, and for use as a dietary supplement.

Basis for the GRAS Determination

Introduction

The regulatory framework for determining whether a substance can be considered generally recognized as safe (GRAS) in accordance with section 201(s) (21 U.S.C. § 321(s)) of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. § 301 et. Seq.) ("the Act"), is set forth at 21 CFR 170.30, which states:

> General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.
>
> General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain

approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information.

These criteria are applied in the analysis below to determine whether the use of the DHA-rich algal oil and powder products for use in foods and infant formula (pre-term and term infants) are GRAS based upon scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FD&C Act.

Safety Determination

DHA and DHA algal oils are currently marketed for use in food for human consumption, including infant formula, as well as dietary supplements. The proposed DHA algal oil and encapsulated powder from *Schizochytrium* sp. T18 has a similar composition and lipid (fatty acid and sterol) profile to that of currently approved/marketed DHA oils from *Schizochytrium* sp. and other algal and marine sources. Regulatory authorities have reviewed the extensive safety study database of DHA and DHA algal and fish oils and found no issues of concern with respect to their use in human food including infant formula. Numerous studies have been conducted and published in support of the evaluation of the safety of DHA and DHA algal and fish oils, including *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, reproductive and developmental toxicity, mutagenicity and genotoxicity, chronic toxicity, carcinogenicity, irritation/sensitization), as well as clinical studies in infants and adults.

DHA-rich oils from numerous sources including microalgae are considered GRAS for use in food for human consumption (GRNs 41, 137, 138, 319, 384, 469, 527, 553, 677), including infant formula (FDA 2003b; 2011b; 2014a, 2014b, 2018a, 2018b). Two other GRAS notifications for DHA-rich oils from microalgae are pending (GRNs 731, 732). Sources of the DHA-rich algal oils include *Schizochytrium* sp., *Crypthecodinium cohnii*, *Ulkenia* sp. SAM2179. Other algal oil sources of food ingredients include *Chlorella protothecoides* strain S106, and *Prototheca moriformis* strain S2532. In addition, FDA has approved other sources of DHA for use in human food and/or infant formula, such as menhaden and fish oils.

In Europe, DHA rich oils from micro-algal sources have been the subject of several authorization decisions and/or notifications under the EU Novel Food Regulation 258/97. Most recently, a Novel Food Application was approved for the use of DSM's DHASCO-B from *Schizochytrium* sp. in conventional foods, infant formula and follow-up formula, and food supplements (DSM, 2013; EU, 2015). The first authorized the use of DHA-rich oil from the thraustochytrid microalgae *Schizochytrium* sp. in a range of foodstuffs and established a specification for the material. The second was for a DHA-rich oil derived from a second thraustochytrid microalgae *Ulkenia* sp. on the grounds of its substantial equivalence with the oil from *Schizochytrium* sp. The other decisions authorized extensions to the approved food uses of the oils from *Ulkenia* sp. and *Schizochytrium* sp.,

respectively. An additional DHA-rich oil derived from the microalgae *Crypthecodinium cohnii* was already on the EU market before the Novel Food Regulation came into effect and was therefore legally and safely in use without the need for explicit approval. It should also be noted that in 2012, the UK Food Standards Agency concluded that T18 algal oil met the criteria for equivalence the currently marketed DHA algal oils as defined in Article 3(4) of regulation (EC) 258/97 and that the *Schizochytrium* strain used in the production of T18 oil was closely related to the organism used in the production of other *Schizochytrium* sp. DHA-rich algal oils (Food Standards Agency, 2012). To date, algal oil produced from *Schizochytrium* sp. has been approved for direct use in foods by the U.S. FDA, Health Canada, European Union, Food Standards Agency of Australia, China's Ministry of Health, and Brazil's National Health Surveillance Agency (FDA, 2014a).

The safety of orally administered DHA from many different sources (e.g., fish oil) including BASF's proposed algal source (*Schizochytrium sp.* T18) have been extensively characterized in the publicly available preclinical and clinical study literature. The compositional profile of the proposed DHA-rich algal oil and encapsulated powder products from T18 present no obvious safety concerns. Finally, similar DHA products have been reviewed and approved around the world for addition to food and infant formula.

General Recognition of the Safety of DHA Algal Oil

The intended use of a DHA-rich algal oil and encapsulated powder has been determined to be safe through scientific procedures as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination and is based on the following:

- The DHA product that is the subject of this GRAS determination is extracted and refined oil or encapsulated powder from the wild-type heterotrophic microalgae *Schizochytrium* sp. T18. It is a mixture of triglycerides containing mostly PUFA in which the predominant fatty acid (>35%) is DHA. The DHA manufacturing process starts with fermentation followed by refining of the crude DHA algal oil isolated from the fermentation process. The DHA algal oil product is manufactured consistent with cGMP for food (21 CFR Part 110 and Part 117 Subpart B). The raw materials and processing aids used in the manufacturing process are food grade and/or commonly used in fermentation and food manufacturing processes.

- The possible presence of microalgae toxins from *Schizochytrium* sp. has been previously addressed as part of a substantial equivalence submission (ONC, 2011) and in GRAS Notification (GRN) No. 553 (FDA, 2014a). Toxin production is unlikely since there are no known reports of toxin production by thraustochytrids, of which *Schizochytrium* is a member (ONC, 2011; Hammond et al., 2002). In addition, T18 oil and algal biomass were screened for the presence of toxins including domoic acid, gymnodimine, desmethyl spirolide C, azaspiracid-1,

azaspiracid-2, azaspiracid-3, pectenotoxin-2, okadaic acid, dinophysistoxin-1, dinophysistoxin-2, yessotoxin, prymnesin-1, and prymnesin-2, and none were detected (ONC, 2011). In addition, BASF has tested several batches of DGA algal oil for the presence of ASP-toxin, domoic acid; okadaic acid; PSP-toxin, saxitoxin; and DTX-1 and the levels were reported to below the level of quantitation of the test methods.

- There is common knowledge of a long history of human consumption of DHA from food and foods containing added DHA, from infant formula, and other products such as dietary supplements. It will be added to food and infant formula for pre-term and term infants in order to supplement the dietary intake of the omega-3 fatty acid DHA. in order to increase the dietary intake of the omega-3 fatty acid DHA.

- Literature searches did not identify safety/toxicity concerns related to any individual fatty acid or their ratios in the proposed DHA algal oil. The proposed DHA oil is similar in fatty acid profile to other commercially available edible oils incorporated in foods and infant formulas and to other algal oils and fish oils (e.g., krill oil) that are currently used in food and/or infant formula.

- The proposed uses of the DHA algal oil and powder products in from *Schizochytrium* sp. T18 in food are identical to the approved uses for other GRAS DHA and/or EPA products. As with the use of menhaden oil, the maximum levels of use were designed to assure that the combined daily intake of the two fatty acid components (i.e., EPA and DHA) would not exceed 3 grams per person per day. In the event a manufacturer blends BASF's DHA-rich algal oil or powder with another oil that is a source of DHA and/or EPA, such a mixture would meet FDA's daily exposure criteria provided that (1) the DHA-rich algal oil is used at a level that would not result in an exposure of more than 1.5 grams of DHA per day and (2) the other oil source of DHA and/or EPA is used at a level that would not result in a cumulative exposure of DHA and EPA greater than 3.0 grams per person per day. Since the proposed DHA algal oil contains approximately 40% DHA compared to about 20% combined EPA and DHA in menhaden oil, the use levels need to be reduced to 25% (as described in Table 9) of the menhaden oil use levels to account for the 50% percent use level for DHA only, and the difference in concentration of DHA in the proposed algal oil (40%) compared to the concentration of EPA and DHA in menhaden oil (20%). A similar adjustment would be made for the algal oil powder product that contains a lower concentration of DHA.

- The proposed uses of the DHA algal oil and encapsulated powder from *Schizochytrium* sp. T18 in infant formula are identical to the approved uses for other GRAS DHA (and/or in combination with ARA) products incorporated in exempt (pre-term or term) and non-exempt (term) infant formula.

- DHA-rich oils from numerous sources including microalgae are considered GRAS for use in food for human consumption (GRNs 41, 137, 138, 319, 384, 469, 527, 553, 677), including infant formula (FDA 2003b; 2011b; 2014a, 2014b, 2018a, 2018b). Two other GRAS notifications for DHA-rich oils from microalgae are pending (GRNs 731). Sources of the DHA-rich algal oils include *Schizochytrium* sp., *Crypthecodinium cohnii*, *Ulkenia* sp. SAM2179. Other algal oil sources of food ingredients include *Chlorella protothecoides* strain S106, and *Prototheca moriformis* strain S2532. In addition, FDA has approved other sources of DHA for use in human food and/or infant formula, such as menhaden and fish oils.

- Toxicity testing has been conducted with the proposed DHA-rich algal oil product from *Schizochytrium* sp. T18 and includes acute and subchronic toxicity studies, a battery of genotoxicity studies, and developmental and reproductive toxicity studies. In all of the studies, no evidence of toxicity was noted at the highest dose levels tested, doses approximately 100x or more higher than those proposed for infant formula (i.e., 27-33 mg.kg/day).

- The publicly available scientific literature on the consumption and safety of DHA and DHA algal oil ingredients, in clinical studies in infants and adult humans as well as animals, is extensive and sufficient to support the safety and GRAS status of the proposed DHA algal oil product.

Since this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of the DHA-rich algal oils that are the subject of this self-determination has been made by BASF. BASF has commissioned ToxStrategies to critically review and evaluate the publicly available information summarized in this document and has concluded that the proposed DHA-rich algal oil and algal oil powder products, produced consistent with cGMP and meeting the specifications described herein, are safe under their intended conditions of use. BASF also concludes that these uses of the DHA algal oil products are GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions.

BASF has concluded that the DHA-rich algal oil and algal oil powder products are GRAS under the intended conditions of use on the basis of scientific procedures; and therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

BASF is not aware of any information that would be inconsistent with a finding that the proposed use of the DHA-rich algal oil and algal oil powder products in food for human

consumption meeting appropriate specifications, and used according to GMP, are GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

§ 170.250 Part 7, Supporting Data and Information

The following references are all generally available, unless otherwise noted. Appendices A and B (analytical COAs for DHA algal oil and stability testing data) are not generally available but are attached for reference.

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APPENDIX A

Certificates of Analysis

TABLE OF CONTENTS

BASF

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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5750**
Production date	**2017-01-17**
Date of analysis	**2017-01-27 to 2017-02-22**

Specification Parameter and Further Tests

Results

Specification Parameter	Unit	Specification limit	Test result	Test method
Acid value	mg KOH/g	≤ 0.5	0.04	ISO 660
Peroxide value	meq O2/kg	≤ 4.0	0.5	ISO 3960
Unsaponifiable matter	%	≤ 35	0.8	PhEur 2.5.7
Moisture (Karl Fischer)	%	≤ 0.05	<0.01	DGF C-III 13a
Fatty acid C22:6 DHA as triglyceride	mg/g	≥ 380	444	PhEur 2.4.29
Trans fatty acids	area-%	≤ 1.0	0.1	IA-005057 *
Total tocopherols	mg/kg	not specified	2849	DIN EN ISO 9936 mod.
Anisidine value	-	≤ 15	1.5	DIN EN ISO 6885
Iron (Fe)	mg/kg	≤ 0.2	<0.1	DIN EN ISO 8294
Copper (Cu)	mg/kg	≤ 0.05	<0.01	DIN EN ISO 8294
Further Tests				
Free fatty acids	%	not specified	0.02	AOCS Ca 5a-40
Colour Gardner	-	not specified	4.9	DGF C-IV 4c
Ash (600°C)	%	not specified	0.0	DGF-C-III 10

* internal test method (GC-FID)

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

[redacted]

Dr. Edith von Kries
QC Manager

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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5750**
Production date	**2017-01-16**
Date of analysis	**2017-02-01**

Tocopherol Assay and Tocopherol Composition

Test method DIN EN ISO 9936 mod.

Results

Tocopherols	in mg/kg
alpha-tocopherol	462
beta-tocopherol	53
gamma-tocopherol	1662
delta-tocopherol	673
total tocopherols	2849

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

BASF
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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5750**
Production date	**2017-01-16**
Date of analysis	**2017-02-17**

Sterol Assay and Sterol Composition

Test method IA-000014 mod. (GC-FID)

Results

Total Sterols 0.2 weight-%

Sterol Isomer	Area-%
Cholestanol	<0.1
Cholesterol	9.0
Brassicasterol	3.2
24-Methylencholesterol	2.4
Campesterol	3.5
Campestanol	<0.1
Stigmasterol	9.3
D7-Campersterol	5.5
D5,23-Stigmastadienol	0.9
Clerosterol	12.1
Beta-Sitosterol	18.3
Sitostanol	<0.1
D5-Avenasterol	6.1
D5,24-Stigmastadienol	9.8
D7-Stigmastenol	14.8
D7-Avenasterol	5.4

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

BASF

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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5750**
Production date	**2017-01-16**
Date of analysis	**2017-02-17**

Fatty Acid Composition

Test method PhEur 2.4.29 (GC-FID)

Units all values expressed in area-%

Myristic acid C14:0	8.9
Palmitic acid C16:0	20.8
Palmitoleic acid C16:1 c9	4.2
Stearic acid C18:0	0.7
Oleic acid C18:1 c9	1.5
C18:1 total (oleic and cis-vaccenic acid)	7.2
Linoleic acid C18:2 c9,c12 n6	0.5
Alpha-linolenic acid C18:3 c9,c12,c15 n3	0.2
Stearidonic acid C18:4 c6,c9,c12,c15 n3	0.3
Arachidic acid C20:0	<0.1
C20:1 sum	<0.1
Arachidonic acid C20:4 n6	0.3
Eicosapentaenoic acid C20:5 n3	1.5
Heneicosapentaenoic acid C21:5 c18 n3	<0.1
Behenic acid C22:0	<0.1
Cetoleic acid C22:1 c11	<0.1
Erucic acid C22:1 c13	not detected
Docosapentaenoic acid C22:5 c16 n6	8.4
Docosapentaenoic acid C22:5 c19 n3	0.3
Docosahexaenoic acid C22:6 n3	45.5
Lignoceric acid C24:0	<0.1
Nervonic acid C24:1 c15	<0.1
Trans fatty acids	0.1

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

eurofins
WEJ Contaminants

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BASF Personal Care and Nutrition GmbH
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Person in charge Ms D. Zarthe - 2907
Client support Ms D. Zarthe - 2907

Report date 20.02.2017

Analytical report: AR-17-JC-029171-02

This report replaces report number: AR-17-JC-029171-01

Sample Code 706-2017-00640080

Reference	DHA Algal Oil DH 5750
Client Sample Code	93420
Purchase Order Code	4935285868
Client contract reference	Rahmenbestell-Nr. 4935285868
Number	1
Amount	75 g
Reception temperature	room temperature
Ordered by	Qualitätskontrolle
Submitted by	Frau Edith von Kries
Sender	DHL
Reception date time	16.02.2017
Packaging	plastic container with plastic closure
Start/end of analyses	16.02.2017 / 20.02.2017

TEST RESULTS

Physical-chemical Analysis

JJ04T Phthalate + DEHA (#)

Method: Internal method, CON-PV 00629, GC-MS

Diethyl hexyl phthalate (DEHP)	<1	* mg/kg
Dimethyl phthalate (DMP)	<1	* mg/kg
Diethyl phthalate (DEP)	<1	* mg/kg
Dibutyl phthalate (DBP)	<0.3	** mg/kg
Di-isobutyl phthalate (DiBP)	<0.3	** mg/kg
Benzyl butyl phthalate (BBP)	<1	* mg/kg
Dioctyl phthalate (D-n-OP)	<1	* mg/kg
DINCH	<5	* mg/kg
Diisononylphthalate (DINP)	<5	* mg/kg
Diisodecylphthalate (DIDP)	<5	* mg/kg
Diethylhexyl adipate (DEHA)	<1	* mg/kg
Triisobutyl phosphate	<1	* mg/kg
Acetyltributylcitrat (ATBC)	<1	* mg/kg

* = Below indicated quantification level

** = Below indicated detection level

(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test.

Result +/- expanded measurement uncertainty (95%; k=2)

WEJ Contaminants

This report replaces report number: AR-17-JC-029171-01

Signature

Analytical Service Manager (Doris Zarthe)

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Person in charge Ms D. Zarthe -2907
Client support Ms D. Zarthe -2907

Report date 27.02.2017

Analytical report: AR-17-JC-032947-02

This report replaces report number: AR-17-JC-032947-01

Sample Code 706-2017-00640079

Reference	DHA Algal Oil DH 5750
Client Sample Code	93420
Purchase Order Code	4935285868
Client contract reference	Rahmenbestell-Nr. 4935285868
Number	1
Amount	195 g
Reception temperature	room temperature
Ordered by	Qualitätskontrolle
Submitted by	Frau Edith von Kries
Sender	DHL
Reception date time	16.02.2017
Packaging	plastic container with plastic closure
Start/end of analyses	16.02.2017 / 23.02.2017

TEST RESULTS

Physical-chemical Analysis

J1001	**Sample preparation (#)**			
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)			
JCM03	**Lead (Pb) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Lead (Pb)		<0.02	*	mg/kg
J8308	**Cadmium (Cd) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Cadmium (Cd)		<0.01	*	mg/kg
JCHG2	**Mercury (Hg) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Mercury (Hg)		<0.005	*	mg/kg
J8312	**Arsenic (As) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Arsenic (As)		<0.1	*	mg/kg
J1042	**Copper (Cu) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Copper (Cu)		<0.1	*	mg/kg
J1043	**Iron (Fe) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Iron (Fe)		<0.5	*	mg/kg

This report replaces report number: AR-17-JC-032947-01

JJ0CG	**Chromium (Cr) (#)**		
Method:	DIN EN ISO 17294-2-E29, CON-PV 00857, ICP-MS		
Chromium (Cr)		<0.05	* mg/kg
J1049	**Nickel (Ni) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Nickel (Ni)		<0.1	* mg/kg
J1047	**Manganese (Mn) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Manganese (Mn)		<0.1	* mg/kg
J1050	**Phosphorus (P) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Phosphorus (P)		<3	* mg/kg
J1054	**Sulphur (S) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Sulphur total (S)		<2	* mg/kg
J1056	**Silicon (Si) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Silicon (Si)		13	mg/kg
		± 3	mg/kg
J1011	**Molybdenum (Mo) (#)**		
Method:	§64 LFGB L00.00-19/3, CON-PV 00508, GF-AAS		
Molybdenum (Mo)		<0.2	* mg/kg

GF08T MS/MS ~ PCDD/F ~ 17 congeneres ~ food / feed

Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

2,3,7,8-TetraCDD	< 0.031	pg/g
1,2,3,7,8-PentaCDD	< 0.041	pg/g
1,2,3,4,7,8-HexaCDD	< 0.062	pg/g
1,2,3,6,7,8-HexaCDD	< 0.085	pg/g
1,2,3,7,8,9-HexaCDD	< 0.080	pg/g
1,2,3,4,6,7,8-HeptaCDD	< 0.13	pg/g
OctaCDD	< 0.95	pg/g
2,3,7,8-TetraCDF	< 0.25	pg/g
1,2,3,7,8-PentaCDF	< 0.059	pg/g
2,3,4,7,8-PentaCDF	< 0.092	pg/g
1,2,3,4,7,8-HexaCDF	< 0.096	pg/g
1,2,3,6,7,8-HexaCDF	< 0.088	pg/g
1,2,3,7,8,9-HexaCDF	< 0.065	pg/g
2,3,4,6,7,8-HexaCDF	< 0.080	pg/g
1,2,3,4,6,7,8-HeptaCDF	< 0.092	pg/g
1,2,3,4,7,8,9-HeptaCDF	< 0.064	pg/g
OctaCDF	< 0.20	pg/g
WHO(2005)-PCDD/F TEQ (upper-bound)	0.185	pg/g

GF09T MS/MS ~ PCB ~ dioxin-like / 12 WHO ~ food / feed

Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

PCB 77	< 2.9	pg/g
PCB 81	< 0.44	pg/g
PCB 105	< 6.4	pg/g
PCB 114	< 0.87	pg/g
PCB 118	< 23	pg/g
PCB 123	< 0.65	pg/g
PCB 126	< 0.41	pg/g

This report replaces report number: AR-17-JC-032947-01

PCB 156		< 3.6	pg/g
PCB 157		< 0.67	pg/g
PCB 167		< 1.8	pg/g
PCB 169		< 2.0	pg/g
PCB 189		< 0.65	pg/g
WHO(2005)-PCB TEQ (upper-bound)		0.101	pg/g

GF004 WHO-PCDD/F+PCB TEQ

Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, Calculation

Subcontracted to a Eurofins laboratory accredited for this test.

WHO(2005)-PCDD/F+PCB TEQ (upper-bound)		0.286	pg/g

GF10T MS/MS ~ PCB ~ 6 ndl ~ food / feed

Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

PCB 28		< 0.16	ng/g
PCB 52		< 0.16	ng/g
PCB 101		< 0.16	ng/g
PCB 138		< 0.16	ng/g
PCB 153		< 0.16	ng/g
PCB 180		< 0.16	ng/g
Total 6 ndl-PCB (upper-bound)		0.980	ng/g

JCP01 Preparation PAH (Caffeine complexation) (#)

Method: Internal method, CON-PV 01176, Extraction

JC00U PAH 4 (#)

Method: Internal method, CON-PV 01176, GC-MS

Benzo(a)anthracene		<0.5	* µg/kg
Benzo(a)pyrene		<0.5	* µg/kg
Benzo(b)fluoranthene		<0.5	* µg/kg
Chrysene		<0.5	* µg/kg
Sum PAH 4	Inapplicable		

JJL3K Shellfish Poisons ASP, PSP, Okadaic acid, Dinophysistoxins

Method: BVL L 12.03/04-1/3/4, , LC-MS/MS

Subcontracted to an external laboratory

Amnesic Shellfish Poison, Domoic acid		<1	* mg/kg
Okadaic acid		<5	* µg/kg
Paralytic Shellfish Poison, Saxitoxin		<20	* µg/kg
DTX-1		<5	* µg/kg

A0428 Aflatoxins B1, B2, G1, G2 (Baby food, dietary food) (#)

Method: EN 15851, mod., CON-PV 00855, IAC-LC-FLD

Aflatoxin B1		<0.01	* µg/kg
Aflatoxin B2		<0.01	* µg/kg
Aflatoxin G1		<0.01	* µg/kg
Aflatoxin G2		<0.01	* µg/kg
Sum of all positive Aflatoxins		<0.04	* µg/kg

* = Below indicated quantification level

(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test

Result +/- expanded measurement uncertainty (95%; k=2)

Signature

Analytical Service Manager (Doris Zarthe)

neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
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Modena (Italy), li 01/03/2017 Page 1 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

Description provided by Customer: DHA ALGAL OIL DH 5750 - SAMPLE-NO.: 93420 - SAMPLE ARRIVED ON 16/02/2017- THE SAMPLE HAS BEEN TAKEN BY THE CUSTOMER. THE TRANSPORT HAS BEEN MADE BY CARRIER.
Sample Condition on Receipt: Room temperature

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
QuEChERS Basic - Nuts, oleaginous seeds and oil BIO								
Flonicamid (LCMS)	< LQ			mg/kg	0,003		* lcms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Flonicamid metabolite: TFNA	< LQ			mg/kg	0,003		* lcms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Flonicamid metabolite: TFNG	< LQ			mg/kg	0,003		* lcms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Abamectin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acetamiprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acetochlor	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acibenzolar-S-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Aclonifen	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Acrinathrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Alachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Aldrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Dieldrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Aldrin and dieldrin, sum expressed in dieldrin [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Ametryn	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine-desethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine-desisopropyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azadirachtin-A	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azinphos-ethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azinphos-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azoxystrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Benalaxyl, sum of isomers including Benalaxyl-M	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Benfluralin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Benomyl, Carbendazim sum expressed as Carbendazim [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbendazim	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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ANALYTICAL AND TECHNICAL SERVICES

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QS-Labor für Futtermittel.

ACCREDIA
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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Benthiavalicarb-isopropyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Bifenazate	< LQ			mg/kg	0,010		+ lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Bifenox	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Bifenthrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bitertanol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Boscalid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Bromophos-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromophos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromopropylate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromuconazole, sum of cis- and trans-isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bupirimate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Buprofezin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Butylate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cadusaphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbaryl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran (including any carbofuran generated from carbosulfan, benfuracarb or furathiocarb)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran-3-hydroxy	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran and Carbofuran-3-hydroxy, sum expressed as Carbofuran [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlordane cis	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane oxi	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane trans	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane sum of cis and trans-isomers [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorfenvinphos, sum of E and Z isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlormephos	< LQ			mg/kg	0,010		+ GCMS-Q 2018 Rev.1 - GC-MS/MS	27/02/2017
Chlorotoluron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlorpropham	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorpyriphos ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorpyriphos methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorsulfuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlorthal dimethyl	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Clofentezine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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ACCREDIA
LAB N°0024

Modena (Italy), li 01/03/2017 Page 3 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Chlorantraniliprole (DPX E-2Y45)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Coumaphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyanazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyazofamide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cycloate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cycloxydim	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyfluthrin e Cyfluthrin beta, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cyhalothrin lambda, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cymoxanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cypermethrin, including other mixtures of constituent isomers (sum of isomers)	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cyproconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyprodinil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
o,p'-DDD	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDD	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
o,p'-DDE	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDE	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
o,p'-DDT	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDT	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
DDT, sum, of pp'-DDT, op'-DDT, pp'-DDE, pp'DDD expressed as DDT [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Deltamethrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Diazinon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichlobenil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Dichlofluanid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichlofluanid and DMSA, sum expressed as dichlofluanid [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethyl-sulfanilide (DMSA)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichloran	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Dichlorvos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dietofencarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Difenoconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Diflubenzuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

OS-feedmonitoring
OS-residuemonitoring
OS-Labor für Frisches Obst, Gemüse und Kartoffeln.
OS-Labor für Futtermittel.

ACCREDIA
LAB. N°0825

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CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Diflufenican	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethenamid, sum of isomers including dimethenamid-P	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethoate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Omethoate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethoate and Omethoato, sum expressed as dimethoate [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethomorph, sum of isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Ditalimfos	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Diuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dodine	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Emamectin benzoate B1a, value expressed as emamectin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Endosulfan alpha	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulfan beta	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulfan sulphate	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulphan, sum of alpha and beta isomers and of endosulfan sulphate, expressed as endosulfan [414]	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Epoxyconazol	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
EPTC	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Esfenvalerate and Fenvalerate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethofumesate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethoprophos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Etofenprox	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Etoxazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Famoxadone	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenamidone	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenamiphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenamiphos-sulfoxide	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fenamiphos-sulfone	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017

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neotron
ANALYTICAL AND TECHNICAL SERVICES

OS-feedmonitoring
OS-residuemonitoring
OS-Labor für Frisches Obst, Gemüse und Kartoffeln
OS-Labor für Futtermittel

ACCREDIA
LAB N°0026

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CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	RSD %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Fenamiphos, fenamiphos-sulfone, fenamiphos-sulfoxide, sum expressed as fenamiphos [414]	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fenarimol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenazaquin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenbuconazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos-oxon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos and fenchlorphos-oxon sum expressed as fenchlorphos [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenhexamid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenitrothion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenoxaprop-p-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenoxycarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenpropathrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenpropidin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenpropimorph	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenpyroximate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion, fenthion-oxon, fenthion-oxon-sulfone, fenthion-oxon-sulfoxide, fenthion-sulfone, fenthion-sulfoxide, sum expressed as fenthion [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Flazasulfuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Flucythrinate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fludioxonil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Flufenacet	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Flufenoxuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fluopicolide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fluquinconazole	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Flusilazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel.

ACCREDIA
LAB. N°0078

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Flutriafol	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fluvalinate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fonofos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Formothion	< LQ			mg/kg	0,010		* icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fosthiazate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
HCH alpha	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH beta	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH delta	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH epsilon	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH, sum of HCH alpha, beta, delta and epsilon [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor Epoxide cis	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor Epoxide trans	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor, Heptachlor Epoxide cis and Epoxide trans sum expressed as Heptachlor [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptenophos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Hexachlorobenzene	< LQ			mg/kg	0,002		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Hexaconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Hexythiazox	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Imazalil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Imidacloprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Indoxacarb, sum of R and S isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Iodofenphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Iprodione	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Iprovalicarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Isofenphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Isofenphos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Isoprothiolane	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Isoproturon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Kresoxim-methyl	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Lindane	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Lindane, sum of HCH isomers included Lindane [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst Gemüse und Kartoffeln.
QS-Labor für Futtermittel

ACCREDIA
LAB. N°0076

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CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Linuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Lufenuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malaoxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malathion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malathion and Malaoxon sum expressed as Malathion [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mandipropamid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mecarbam	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mepanipyrim	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metalaxyl, sum of isomers including Metalaxyl-M	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metazachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Methidathion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Methiocarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb, methiocarb sulfone and methiocarb sulfoxide, sum expressed as Methiocarb [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methomyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiodicarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methomyl and Thiordicarb sum expressed as Methomyl [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methoxychlor	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Methoxyfenozide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Metolachlor, sum of isomers including S-metolachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metrafenone	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Metribuzin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metsulfuron-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mevinphos, sum of cis- and trans-isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Molinate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Monuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

Continued...

neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB. N°0026

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CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	Unit OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Myclobutanil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Napropamide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Oxadiazon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Oxadixyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Oxyfluorfen	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paclobutrazol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paraoxon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paraoxon-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion and Paraoxon sum expressed as Parathion [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion-methyl and Paraoxon-methyl sum expressed as Parathion-methyl [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Penconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pencycuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pendimethalin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Permethrin, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Perthane	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Phenmedipham	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phenthoate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Phorate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate, phorate-oxon, phorate-sulfone and phorate-sulfoxide, sum expressed as phorate [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosalone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet and phosmet-oxon expressed as phosmet [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosphamidon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Picoxystrobin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Piperonyl butoxide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017

Continued...

neotron
ANALYTICAL AND TECHNICAL SERVICES

OS-feedmonitoring
OS-residuemonitoring
OS-Labor für Frisches Obst, Gemüse und Kartoffeln
OS-Labor für Futtermittel

ACCREDIA
LAB. N°0024

Modena (Italy), li 01/03/2017 Page 9 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Pirimicarb (Pirimor)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimicarb-desmethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimicarb and pirimicarb-desmethyl, sum expressed as pirimicarb [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimiphos-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Pirimiphos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Prochloraz	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Procymidone	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Profenofos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Prometryn	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propachlor	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propaquizafop	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propargite	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propiconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propoxur	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propyzamide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Proquinazid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyraclostrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyrazophos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyrethrins: pyrethrin I and II, cinerin I and II, jasmolin I and II, sum (low limit)	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Pyridaben	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Pyrimethanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyriproxyfen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Quinalphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Quinoxifen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Quintozene	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Pentachloroaniline	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Quintozene and pentacloroanilin, sum expressed as quintozene [414]	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

Continued...

neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel.

ACCREDIA
LAB. N°0026

Modena (Italy), li 01/03/2017 Page 10 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Rotenone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Simazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spinosad, sum of spinosyn A and spinosyn D	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirodiclofen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirotetramat	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirotetramat enol	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat enol-glucoside	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat ketohydroxy	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat monohydroxy	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat and its metabilites (enol, enol-glucoside, ketohydroxy, monohydroxy) sum as spirotetramat [414]	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spiroxamine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Sulfallate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Sulfotep	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Tebuconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tebufenozide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tebufenpyrad	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Teflubenzuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tefluthrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Terbuthylazine	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Tetrachlorvinphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tetraconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tetradifon	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Tetramethrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Thiabendazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiacloprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiamethoxam	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiobencarbe	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Thionazin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB. N°0076

Modena (Italy), li 01/03/2017 Page 11 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Thiophanate-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tolclofos-methyl	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Tolylfluanid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethylaminosulphotoluidide (DMST)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tolylfluanid and DMST, sum expressed as tolylfluanid [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triadimefon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triadimenol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triadimefon and Triadimenol, sum [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triallate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Di-allate (sum of isomers)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triallate and Diallate sum expressed as Triallate [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triazophos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trichlorfon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tricyclazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trifloxystrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triflumuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trifluralin	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Triticonazole	< LQ			mg/kg	0,010		GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Vamidothion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Vinchlozolin	< LQ			mg/kg	0,005		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

Continued...

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAS. N°0025

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12442-In-0

SAMPLE 17B12442

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSIS ENDING DATE
Zoxamide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

END TEST REPORT

Notes and method reference:
< LQ: = lower than Quantification Limit. Please note that results expressed as '<LQ' may not indicate the absence of the searched parameters in the sample.
U: the reported uncertainty is the expanded uncertainty calculated using a coverage factor equal to 2 which gives a reliability of approximately 95%. For microbiological detections it is reported either the lower and the upper bounds of the confidence interval with a probability of 95% K=2 or the confidence interval itself.
Results coming from microbiological tests are calculated according to the Standard ISO 7218:2007/Amd 1:2013. If the results are reported as <4 (CFU/ml) or <40 (CFU/g), this means that the microorganisms are present in the sample but in amounts less than 4 CFU/ml or 40 CFU/g respectively.
LQ: Quantification Limit. It is the lowest analyte concentration which can be detected at an acceptable precision (repeatability) and accuracy, under well defined conditions.
LD: Detection Limit. It is the lowest analyte concentration which can be detected but not necessarily quantified, under well defined conditions.
Conformity evaluation: values not complying with laws, decrees, national and EU regulations or specifications supplied by the customer are evaluated case by case, also taking into consideration the uncertainty of measure for each single test and the regulations on rounding-off of values, and pointed out when considered as "non conform".
Rec %: Recovery % "+" means that the recovery has been applied to the result. The numeric results between brackets (..) after the espression <LQ are purely indicative of traces that cannot be exactly quantified.
Methods marked with an asterisk (*) are not accredited by ACCREDIA (UNI CEI EN ISO/IEC 17025)

NOTES OF PARAMETERS:
[414]: The sum is calculated through the lower bound criterion.

LABORATORY MANAGER: DR. GIAN CARLO GATTI - MEMBER OF AOAC N. VM 90231001 - EURCHEM
Approved by Analysis Manager - laboratory LMIA-post

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LS|AG

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Akkreditiert nach ISO / IEC 17025

Durch die DAkkS Deutsche Akkreditierungsstelle GmbH nach DIN EN ISO/IEC 17025 akkreditiertes Prüflaboratorium. Die Akkreditierung gilt für die in der Urkunde aufgeführten Verfahren.

DAkkS Deutsche Akkreditierungsstelle D-PL-14559-01-01 D-PL-14559-01-02

Bad Bocklet 22 Feb 2017 / MEZ / Basfil

mblabor@basf.com

Certificate of Analysis

L+S No:	170216-0021-003	**L+S Code:**	0817357 / L
Product name:	DHA Algal Oil / Algenöl		
Description:	DH 5750, Blome 93420		
Your Order No:	4915012499		
Order dated:	15 Feb 2017	**Sample receipt:**	16 Feb 2017
Start of test:	17 Feb 2017	**End of test:**	22 Feb 2017

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
coliform bacteria, quantitative	L+S SOP 9.008		not detected / g DIN EN ISO 4831, mod.
Escherichia coli, qualitative	L+S SOP 9.009		not detected / g DIN EN ISO 16649, mod.
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / g DIN EN ISO 21528
total viable count, aerobic mesophilic 30°C	*L 00.00 - 88/2 mod.		< 10 CFU / g DIN EN ISO 4833-2
yeasts, quantitative	*L 01.00 - 37, mod.		< 10 CFU / g DIN EN ISO 21527
Salmonella sp., qualitative	*L 00.00 - 20		not detected / 25 g DIN EN ISO 6579
molds, quantitative	*L 01.00 - 37, mod.		< 10 CFU / g DIN EN ISO 21527
koagulase-positive Staphylokokken, qualitativ	L+S SOP 9.014		not detected / g DIN EN ISO 6888-1, mod.
Pseudomonas aeruginosa, qualitativ	L+S SOP 9.035		not detected / g DIN EN ISO 13720, mod.

LS|AG

L+S No 170216-0021-003 | **L+S Code** 0817357 / L |
Product name DHA Algal Oil / Algenöl

22. FEB. 2017

Dr Christian Arndt
Head of Department

SGS

SGS Germany GmbH Rödingsmarkt 16 20459 Hamburg

BASF Personal Care and Nutrition GmbH
Robert-Hansen-Straße 1
89257 Illertissen

Test Report 3264050
Order No. 4063689
Customer No. 10078225

Mandy Elias
Phone +49 40-30101-680
Fax +49 40-30101-943
mandy.elias@sgs.com

Agriculture, Food

SGS Germany GmbH
Rödingsmarkt 16
20459 Hamburg

DAkkS
Deutsche
Akkreditierungsstelle
D-PL-11020-04-01

Hamburg, 20.02.2017

Your order/project: .
Your purchase order number: 4935280662
Your purchase order date: 15.02.2017

General Information:

Sample No.:	170169209
Sample:	DHA Algal Oil DH 5750 Proben Nr.93420 15.02.2017
Date of receipt:	16.02.2017
Testing period (begin / end):	16.02.2017 / 17.02.2017
Packaging:	Plastic can
Quantity:	64g

Test Results:

Parameter	Method	Lab	Unit	Result	Limit of quantification	Requirements
Special analyses:						
Glycidylester det. as free Glycidol	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	< 10	10	
Sum free 2-MCPD, 2-MCPDester, det. as free 2-MCPD	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	< 10	10	
Sum free 3-MCPD, 3-MCPDester, det. as free 3-MCPD	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	173	10	

The laboratory sites of the SGS group Germany according to the abbreviations mentioned above are listed at http://www.institut-fresenius.de/filestore/89/laborstandortkuerzelsgs2.pdf.

SGS Germany

.....
i.V. Ingrid Bujara / i.V. Dr. Sven-Erik Knopp / i.V. Claudia Koch / i.V. Lars Rückborn
i.A. Catherine Herzog / i.A. Heike Höfelmeier
/ i.A. Mandy Elias (Customer Service Consultants)

BASF

We create chemistry

Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5751**
Production date	**2017-01-17**
Date of analysis	**2017-01-27 to 2017-02-22**

Specification Parameter and Further Tests

Results

Specification Parameter	Unit	Specification limit	Test result	Test method
Acid value	mg KOH/g	≤ 0.5	0.02	ISO 660
Peroxide value	meq O2/kg	≤ 4.0	0.6	ISO 3960
Unsaponifiable matter	%	≤ 35	0.9	PhEur 2.5.7
Moisture (Karl Fischer)	%	≤ 0.05	<0.01	DGF C-III 13a
Fatty acid C22:6 DHA as triglyceride	mg/g	≥ 380	441	PhEur 2.4.29
Trans fatty acids	area-%	≤ 1.0	0.1	IA-005057 *
Total tocopherols	mg/kg	not specified	2814	DIN EN ISO 9936 mod.
Anisidine value	-	≤ 15	1.6	DIN EN ISO 6885
Iron (Fe)	mg/kg	≤ 0.2	<0.1	DIN EN ISO 8294
Copper (Cu)	mg/kg	≤ 0.05	<0.01	DIN EN ISO 8294
Further Tests				
Free fatty acids	%	not specified	0.01	AOCS Ca 5a-40
Colour Gardner	-	not specified	5.9	DGF C-IV 4c
Ash (600°C)	%	not specified	0.0	DGF-C-III 10

* internal test method (GC-FID)

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5751**
Production date	**2017-01-17**
Date of analysis	**2017-02-01**

Tocopherol Assay and Tocopherol Composition

Test method DIN EN ISO 9936 mod.

Results

Tocopherols	in mg/kg
alpha-tocopherol	478
beta-tocopherol	54
gamma-tocopherol	1622
delta-tocopherol	660
total tocopherols	2814

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

BASF
We create chemistry

Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5751**
Production date	**2017-01-17**
Date of analysis	**2017-02-17**

Sterol Assay and Sterol Composition

Test method IA-000014 mod. (GC-FID)

Results

Total Sterols 0.2 weight-%

Sterol Isomer	Area-%
Cholestanol	<0.1
Cholesterol	10.1
Brassicasterol	2.6
24-Methylencholesterol	2.6
Campesterol	4.0
Campestanol	<0.1
Stigmasterol	7.15
D7-Campersterol	5.2
D5,23-Stigmastadienol	1.0
Clerosterol	12.8
Beta-Sitosterol	15.3
Sitostanol	<0.1
D5-Avenasterol	6.0
D5,24-Stigmastadienol	8.8
D7-Stigmastenol	18.6
D7-Avenasterol	6.1

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5751**
Production date	**2017-01-17**
Date of analysis	**2017-02-17**

Fatty Acid Composition

Test method PhEur 2.4.29 (GC-FID)

Units all values expressed in area-%

Myristic acid C14:0	9.5
Palmitic acid C16:0	22.3
Palmitoleic acid C16:1 c9	3.0
Stearic acid C18:0	0.8
Oleic acid C18:1 c9	1.9
C18:1 total (oleic and cis-vaccenic acid)	6.4
Linoleic acid C18:2 c9,c12 n6	0.6
Alpha-linolenic acid C18:3 c9,c12,c15 n3	0.2
Stearidonic acid C18:4 c6,c9,c12,c15 n3	0.3
Arachidic acid C20:0	<0.1
C20:1 sum	<0.1
Arachidonic acid C20:4 n6	0.3
Eicosapentaenoic acid C20:5 n3	1.6
Heneicosapentaenoic acid C21:5 c18 n3	<0.1
Behenic acid C22:0	<0.1
Cetoleic acid C22:1 c11	<0.1
Erucic acid C22:1 c13	not detected
Docosapentaenoic acid C22:5 c16 n6	8.0
Docosapentaenoic acid C22:5 c19 n3	0.3
Docosahexaenoic acid C22:6 n3	45.3
Lignoceric acid C24:0	<0.1
Nervonic acid C24:1 c15	0.1
Trans fatty acids	0.1

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

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BASF Personal Care and Nutrition GmbH
-Standort Illertissen-
Postfach 10 63
89251 Illertissen

Person in charge Ms D. Zarthe - 2907
Client support Ms D. Zarthe - 2907

Report date 20.02.2017

Analytical report: AR-17-JC-029172-02

This report replaces report number: AR-17-JC-029172-01

Sample Code 706-2017-00640082

Reference	DHA Algal Oil DH 5751
Client Sample Code	93419
Purchase Order Code	4935285868
Client contract reference	Rahmenbestell-Nr. 4935285868
Number	1
Amount	76 g
Reception temperature	room temperature
Ordered by	Qualitätskontrolle
Submitted by	Frau Edith von Kries
Sender	DHL
Reception date time	16.02.2017
Packaging	plastic container with plastic closure
Start/end of analyses	16.02.2017 / 20.02.2017

TEST RESULTS

Physical-chemical Analysis

JJ04T Phthalate + DEHA (#)

Method: Internal method, CON-PV 00629, GC-MS

Diethyl hexyl phthalate (DEHP)	<1	* mg/kg
Dimethyl phthalate (DMP)	<1	* mg/kg
Diethyl phthalate (DEP)	<1	* mg/kg
Dibutyl phthalate (DBP)	<0.3	** mg/kg
Di-isobutyl phthalate (DiBP)	<0.3	** mg/kg
Benzyl butyl phthalate (BBP)	<1	* mg/kg
Dioctyl phthalate (D-n-OP)	<1	* mg/kg
DINCH	<5	* mg/kg
Diisononylphthalate (DINP)	<5	* mg/kg
Diisodecylphthalate (DIDP)	<5	* mg/kg
Diethylhexyl adipate (DEHA)	<1	* mg/kg
Triisobutyl phosphate	<1	* mg/kg
Acetyltributylcitrat (ATBC)	<1	* mg/kg

* = Below indicated quantification level

** = Below indicated detection level

(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test.

Result +/- expanded measurement uncertainty (95%; k=2)

WEJ Contaminants

This report replaces report number: AR-17-JC-029172-01

Signature

Analytical Service Manager (Doris Zarthe)

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Person in charge Ms D. Zarthe - 2907
Client support Ms D. Zarthe - 2907

Report date 27.02.2017

Analytical report: AR-17-JC-032948-02

This report replaces report number: AR-17-JC-032948-01

Sample Code 706-2017-00640081

Reference	DHA Algal Oil DH 5751
Client Sample Code	93419
Purchase Order Code	4935285868
Client contract reference	Rahmenbestell-Nr. 4935285868
Number	1
Amount	203 g
Reception temperature	room temperature
Ordered by	Qualitätskontrolle
Submitted by	Frau Edith von Kries
Sender	DHL
Reception date time	16.02.2017
Packaging	plastic container with plastic closure
Start/end of analyses	16.02.2017 / 27.02.2017

TEST RESULTS

Physical-chemical Analysis

J1001	**Sample preparation (#)**			
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)			
JCM03	**Lead (Pb) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Lead (Pb)		<0.02	*	mg/kg
J8308	**Cadmium (Cd) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Cadmium (Cd)		<0.01	*	mg/kg
JCHG2	**Mercury (Hg) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Mercury (Hg)		<0.005	*	mg/kg
J8312	**Arsenic (As) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Arsenic (As)		<0.1	*	mg/kg
J1042	**Copper (Cu) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Copper (Cu)		<0.1	*	mg/kg
J1043	**Iron (Fe) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Iron (Fe)		<0.5	*	mg/kg

This report replaces report number: AR-17-JC-032948-01

JJ0CG	**Chromium (Cr) (#)**		
Method:	DIN EN ISO 17294-2-E29, CON-PV 00857, ICP-MS		
Chromium (Cr)		<0.05	* mg/kg
J1049	**Nickel (Ni) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Nickel (Ni)		<0.1	* mg/kg
J1047	**Manganese (Mn) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Manganese (Mn)		<0.1	* mg/kg
J1050	**Phosphorus (P) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Phosphorus (P)		<3	* mg/kg
J1054	**Sulphur (S) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Sulphur total (S)		3.0	mg/kg
		± 2	mg/kg
J1056	**Silicon (Si) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Silicon (Si)		22	mg/kg
		± 5	mg/kg
J1011	**Molybdenum (Mo) (#)**		
Method:	§64 LFGB L00.00-19/3, CON-PV 00508, GF-AAS		
Molybdenum (Mo)		<0.2	* mg/kg
GF08T	**MS/MS ~ PCDD/F ~ 17 congeneres ~ food / feed**		
Method:	EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
2,3,7,8-TetraCDD		< 0.031	pg/g
1,2,3,7,8-PentaCDD		< 0.041	pg/g
1,2,3,4,7,8-HexaCDD		< 0.063	pg/g
1,2,3,6,7,8-HexaCDD		< 0.086	pg/g
1,2,3,7,8,9-HexaCDD		< 0.081	pg/g
1,2,3,4,6,7,8-HeptaCDD		< 0.13	pg/g
OctaCDD		< 0.95	pg/g
2,3,7,8-TetraCDF		< 0.25	pg/g
1,2,3,7,8-PentaCDF		< 0.059	pg/g
2,3,4,7,8-PentaCDF		< 0.092	pg/g
1,2,3,4,7,8-HexaCDF		< 0.097	pg/g
1,2,3,6,7,8-HexaCDF		< 0.089	pg/g
1,2,3,7,8,9-HexaCDF		< 0.066	pg/g
2,3,4,6,7,8-HexaCDF		< 0.081	pg/g
1,2,3,4,6,7,8-HeptaCDF		< 0.092	pg/g
1,2,3,4,7,8,9-HeptaCDF		< 0.064	pg/g
OctaCDF		< 0.20	pg/g
WHO(2005)-PCDD/F TEQ (upper-bound)		0.186	pg/g
GF09T	**MS/MS ~ PCB ~ dioxin-like / 12 WHO ~ food / feed**		
Method:	EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
PCB 77		< 3.0	pg/g
PCB 81		< 0.44	pg/g
PCB 105		< 6.4	pg/g
PCB 114		< 0.87	pg/g
PCB 118		< 23	pg/g
PCB 123		< 0.66	pg/g

This report replaces report number: AR-17-JC-032948-01

PCB 126		< 0.41	pg/g
PCB 156		< 3.6	pg/g
PCB 157		< 0.67	pg/g
PCB 167		< 1.8	pg/g
PCB 169		< 2.0	pg/g
PCB 189		< 0.66	pg/g
WHO(2005)-PCB TEQ (upper-bound)		0.102	pg/g

GF004 WHO-PCDD/F+PCB TEQ
Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, Calculation
Subcontracted to a Eurofins laboratory accredited for this test.

WHO(2005)-PCDD/F+PCB TEQ (upper-bound)		0.288	pg/g

GF10T MS/MS ~ PCB ~ 6 ndl ~ food / feed
Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS
Subcontracted to a Eurofins laboratory accredited for this test.

PCB 28		< 0.16	ng/g
PCB 52		< 0.16	ng/g
PCB 101		< 0.16	ng/g
PCB 138		< 0.16	ng/g
PCB 153		< 0.16	ng/g
PCB 180		< 0.16	ng/g
Total 6 ndl-PCB (upper-bound)		0.987	ng/g

JCP01 Preparation PAH (Caffeine complexation) (#)
Method: Internal method, CON-PV 01176, Extraction

JC00U PAH 4 (#)
Method: Internal method, CON-PV 01176, GC-MS

Benzo(a)anthracene		<0.5	* µg/kg
Benzo(a)pyrene		<0.5	* µg/kg
Benzo(b)fluoranthene		<0.5	* µg/kg
Chrysene		<0.5	* µg/kg
Sum PAH 4	Inapplicable		

JJL3K Shellfish Poisons ASP, PSP, Okadaic acid, Dinophysistoxins
Method: BVL L 12.03/04-1/3/4, , LC-MS/MS
Subcontracted to an external laboratory

Amnesic Shellfish Poison, Domoic acid		<1	* mg/kg
Okadaic acid		<5	* µg/kg
Paralytic Shellfish Poison, Saxitoxin		<20	* µg/kg
DTX-1		<5	* µg/kg

A0428 Aflatoxins B1, B2, G1, G2 (Baby food, dietary food) (#)
Method: EN 15851, mod., CON-PV 00855, IAC-LC-FLD

Aflatoxin B1		<0.01	* µg/kg
Aflatoxin B2		<0.01	* µg/kg
Aflatoxin G1		<0.01	* µg/kg
Aflatoxin G2		<0.01	* µg/kg
Sum of all positive Aflatoxins		<0.04	* µg/kg

* = Below indicated quantification level
(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test.
Result +/- expanded measurement uncertainty (95%; k=2)

Signature

Analytical Service Manager (Doris Zarthe)

neotron S.p.A.
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel.

ACCREDIA
LAB. N°0026

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

Description provided by Customer: DHA ALGAL OIL DH 5751 - SAMPLE-NO.: 93419 - SAMPLE ARRIVED ON 16/02/2017- THE SAMPLE HAS BEEN TAKEN BY THE CUSTOMER. THE TRANSPORT HAS BEEN MADE BY CARRIER.
Sample Condition on Receipt: Room temperature

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
QuEChERS Basic - Nuts, oleaginous seeds and oil BIO								
Flonicamid (LCMS)	< LQ			mg/kg	0,003		* icms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Flonicamid metabolite: TFNA	< LQ			mg/kg	0,003		* icms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Flonicamid metabolite: TFNG	< LQ			mg/kg	0,003		* icms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Abamectin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acetamiprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acetochlor	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acibenzolar-S-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Aclonifen	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Acrinathrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Alachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Aldrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Dieldrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Aldrin and dieldrin, sum expressed in dieldrin [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Ametryn	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine-desethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine-desisopropyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azadirachtin-A	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azinphos-ethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azinphos-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azoxystrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Benalaxyl, sum of isomers including Benalaxyl-M	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Benfluralin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Benomyl, Carbendazim sum expressed as Carbendazim [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbendazim	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
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QS-Labor für Frisches Obst, Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB N°0625
Signatory of ILAC and EA Mutual Recognition Agreement

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSIS ENDING DATE
Benthiavalicarb-isopropyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Bifenazate	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Bifenox	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Bifenthrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bitertanol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Boscalid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Bromophos-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromophos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromopropylate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromuconazole, sum of cis- and trans-isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bupirimate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Buprofezin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Butylate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cadusaphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbaryl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran (including any carbofuran generated from carbosulfan, benfuracarb or furathiocarb)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran-3-hydroxy	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran and Carbofuran-3-hydroxy, sum expressed as Carbofuran [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlordane cis	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane oxi	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane trans	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane sum of cis and trans-isomers [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorfenvinphos, sum of E and Z isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlormephos	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Chlorotoluron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlorpropham	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorpyriphos ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorpyriphos methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorsulfuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlorthal dimethyl	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Clofentezine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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CUSTOMER
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TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Chlorantraniliprole (DPX E-2Y45)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Coumaphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyanazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyazofamide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cycloate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cycloxydim	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyfluthrin e Cyfluthrin beta, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cyhalothrin lambda, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cymoxanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cypermethrin, including other mixtures of constituent isomers (sum of isomers)	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cyproconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyprodinil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
o,p'-DDD	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDD	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
o,p'-DDE	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDE	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
o,p'-DDT	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDT	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
DDT, sum, of pp'-DDT, op'-DDT, pp'-DDE, pp'DDD expressed as DDT [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Deltamethrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Diazinon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichlobenil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Dichlofluanid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichlofluanid and DMSA, sum expressed as dichlofluanid [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethyl-sulfanilide (DMSA)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichloran	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Dichlorvos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dietofencarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Difenoconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Diflubenzuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel.

ACCREDIA
LAB. N°0026
Signatory of EA, MF and ILAC Mutual Recognition Agreements

Modena (Italy), li 01/03/2017 Page 4 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSIS ENDING DATE
Diflufenican	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethenamid, sum of isomers including dimethenamid-P	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethoate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Omethoate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethoate and Omethoato, sum expressed as dimethoate [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethomorph, sum of isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Ditalimfos	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Diuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dodine	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Emamectin benzoate B1a, value expressed as emamectin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Endosulfan alpha	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulfan beta	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulfan sulphate	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulphan, sum of alpha and beta isomers and of endosulfan sulphate, expressed as endosulfan [414]	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Epoxyconazol	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
EPTC	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Esfenvalerate and Fenvalerate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethofumesate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethoprophos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Etofenprox	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Etoxazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Famoxadone	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenamidone	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenamiphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenamiphos-sulfoxide	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fenamiphos-sulfone	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017

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neotron S.p.A.
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel.

ACCREDIA
LAB. N°0926

Modena (Italy), li 01/03/2017 Page 5 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Fenamiphos, fenamiphos-sulfone, fenamiphos-sulfoxide, sum expressed as fenamiphos [414]	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fenarimol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenazaquin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenbuconazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos-oxon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos and fenchlorphos-oxon sum expressed as fenchlorphos [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenhexamid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenitrothion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenoxaprop-p-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenoxycarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenpropathrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenpropidin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenpropimorph	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenpyroximate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion, fenthion-oxon, fenthion-oxon-sulfone, fenthion-oxon-sulfoxide, fenthion-sulfone, fenthion-sulfoxide, sum expressed as fenthion [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Flazasulfuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Flucythrinate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fludioxonil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Flufenacet	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Flufenoxuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fluopicolide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fluquinconazole	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Flusilazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017

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neotron S.P.A.
ANALYTICAL AND TECHNICAL SERVICES

OS-feedmonitoring
OS-residuemonitoring
OS-Labor für Frisches Obst, Gemüse und Kartoffeln.
OS-Labor für Futtermittel.

ACCREDIA
LAB. N°0076
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Flutriafol	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fluvalinate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fonofos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Formothion	< LQ			mg/kg	0,010		* icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fosthiazate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
HCH alpha	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH beta	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH delta	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH epsilon	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH, sum of HCH alpha, beta, delta and epsilon [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor Epoxide cis	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor Epoxide trans	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor, Heptachlor Epoxide cis and Epoxide trans sum expressed as Heptachlor [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptenophos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Hexachlorobenzene	< LQ			mg/kg	0,002		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Hexaconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Hexythiazox	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Imazalil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Imidacloprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Indoxacarb, sum of R and S isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Iodofenphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Iprodione	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Iprovalicarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Isofenphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Isofenphos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Isoprothiolane	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Isoproturon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Kresoxim-methyl	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Lindane	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Lindane, sum of HCH isomers included Lindane [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-rückstandsmonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel.

ACCREDIA
LAB N°0025
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Linuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Lufenuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malaoxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malathion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malathion and Malaoxon sum expressed as Malathion [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mandipropamid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mecarbam	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mepanipyrim	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metalaxyl, sum of isomers including Metalaxyl-M	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metazachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Methidathion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Methiocarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb, methiocarb sulfone and methiocarb sulfoxide, sum expressed as Methiocarb [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methomyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiodicarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methomyl and Thiordicarb sum expressed as Methomyl [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methoxychlor	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Methoxyfenozide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Metolachlor, sum of isomers including S-metolachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metrafenone	< LQ			mg/kg	0,010		• Ioms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Metribuzin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metsulfuron-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mevinphos, sum of cis- and trans-isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Molinate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Monuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

Continued...

neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

OS-feedmonitoring
OS-residuemonitoring
OS-Labor für Frisches Obst, Gemüse und Kartoffeln.
OS-Labor für Futtermittel.

ACCREDIA
LAB. N°0026
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Myclobutanil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Napropamide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Oxadiazon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Oxadixyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Oxyfluorfen	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paclobutrazol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paraoxon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paraoxon-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion and Paraoxon sum expressed as Parathion [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion-methyl and Paraoxon-methyl sum expressed as Parathion-methyl [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Penconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pencycuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pendimethalin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Permethrin, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Perthane	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Phenmedipham	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phenthoate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Phorate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate, phorate-oxon, phorate-sulfone and phorate-sulfoxide, sum expressed as phorate [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosalone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet and phosmet-oxon expressed as phosmet [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosphamidon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Picoxystrobin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Piperonyl butoxide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017

Continued...

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ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
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QS-Labor für Futtermittel.

ACCREDIA
LAB N°0026

Modena (Italy), li 01/03/2017 Page 9 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Pirimicarb (Pirimor)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimicarb-desmethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimicarb and pirimicarb-desmethyl, sum expressed as pirimicarb [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimiphos-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Pirimiphos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Prochloraz	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Procymidone	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Profenofos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Prometryn	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propachlor	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propaquizafop	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propargite	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propiconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propoxur	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propyzamide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Proquinazid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyraclostrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyrazophos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyrethrins: pyrethrin I and II, cinerin I and II, jasmolin I and II, sum (low limit)	< LQ			mg/kg	0,010		* Icma-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Pyridaben	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Pyrimethanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyriproxyfen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Quinalphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Quinoxifen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Quintozene	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Pentachloroaniline	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Quintozene and pentacloroanilin, sum expressed as quintozene [414]	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

Continued...

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ANALYTICAL AND TECHNICAL SERVICES

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ACCREDIA
LAB. N°0026

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSIS ENDING DATE
Rotenone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Simazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spinosad, sum of spinosyn A and spinosyn D	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirodiclofen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirotetramat	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirotetramat enol	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat enol-glucoside	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat ketohydroxy	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat monohydroxy	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat and its metabilites (enol, enol-glucoside, ketohydroxy, monohydroxy) sum as spirotetramat [414]	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spiroxamine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Sulfallate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Sulfotep	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Tebuconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tebufenozide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tebufenpyrad	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Teflubenzuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tefluthrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Terbuthylazine	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Tetrachlorvinphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tetraconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tetradifon	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Tetramethrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Thiabendazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiacloprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiamethoxam	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiobencarbe	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Thionazin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

Continued...

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Modena (Italy), li 01/03/2017 Page 11 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Thiophanate-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tolclofos-methyl	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Tolylfluanid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethylaminosulphotoluidide (DMST)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tolylfluanid and DMST, sum expressed as tolylfluanid [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triadimefon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triadimenol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triadimefon and Triadimenol, sum [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triallate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Di-allate (sum of isomers)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triallate and Diallate sum expressed as Triallate [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triazophos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trichlorfon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tricyclazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trifloxystrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triflumuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trifluralin	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Triticonazole	< LQ			mg/kg	0,010		e GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Vamidothion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Vinchlozolin	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

Continued...

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ANALYTICAL AND TECHNICAL SERVICES

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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Modena (Italy), li 01/03/2017 Page 12 di 12

CUSTOMER
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TEST REPORT nr. 17B12441-In-0

SAMPLE 17B12441

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Zoxamide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

END TEST REPORT

Notes and method reference:
< LQ: = lower than Quantification Limit. Please note that results expressed as '<LQ' may not indicate the absence of the searched parameters in the sample.
U: the reported uncertainty is the expanded uncertainty calculated using a coverage factor equal to 2 which gives a reliability of approximately 95%. For microbiological detections it is reported either the lower and the upper bounds of the confidence interval with a probability of 95% K=2 or the confidence interval itself.
Results coming from microbiological tests are calculated according to the Standard ISO 7218:2007/Amd 1:2013. If the results are reported as <4 (CFU/ml) or <40 (CFU/g), this means that the microorganisms are present in the sample but in amounts less than 4 CFU/ml or 40 CFU/g respectively.
LQ: Quantification Limit. It is the lowest analyte concentration which can be detected at an acceptable precision (repeatability) and accuracy, under well defined conditions.
LD: Detection Limit. It is the lowest analyte concentration which can be detected but not necessarily quantified, under well defined conditions.
Conformity evaluation: values not complying with laws, decrees, national and EU regulations or specifications supplied by the customer are evaluated case by case, also taking into consideration the uncertainty of measure for each single test and the regulations on rounding-off of values, and pointed out when considered as "non conform".
Rec %: Recovery % "+" means that the recovery has been applied to the result. The numeric results between brackets (..) after the espression <LQ are purely indicative of traces that cannot be exactly quantified.
Methods marked with an asterisk (*) are not accredited by ACCREDIA (UNI CEI EN ISO/IEC 17025)

NOTES OF PARAMETERS:
[414]: The sum is calculated through the lower bound criterion.

TEST REPORT VALID FOR ALL LEGAL PURPOSES (Italian R.D. 1-3-1928 n°842 (article 16), – Italian Law 19-7-1957 n°679 articles 16 and 18, Italian Ministerial Decree 25-3-1986).
Test Report issued according to the 17025:2005 Standard
DATA and SAMPLE STORAGE: Raw data, chromatographic paths and instrumental reports are stored for 5 years. One control sample is stored for 2 months.
Data expressed in this test report refer only to the sample tested in the laboratory. The description or any other reference concerning the sample are declared by the customer. This Test Report cannot be reproduced except in full. Partial reproductions must be authorized in writing by our laboratory.

LABORATORY MANAGER: DR. GIAN CARLO GATTI - MEMBER OF AOAC N. VM 90231001 - EURCHEM
Approved by Analysis Manager - laboratory LMIA-pest

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GMP Pharmaceutical Laboratories Authorized by AIFA Italian Medicine Agency n° aM- 55/2015.
Laboratorio Qualificato D.M. 26-2-87 Art. 4 - Legge 46/82 per la Ricerca Applicata e Innovazione Tecnologica.
Regione Emilia Romagna - AUTORIZZAZIONE Autocontrollo N° 008/MO/008
BNN-Monitoring Fruit and Vegetables Approved Laboratory
I-Monitoring EDEKA AG Fruit and Vegetables Registered Laboratory

LS|AG

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Akkreditiert nach ISO / IEC 17025
Durch die DAkkS Deutsche Akkreditierungsstelle GmbH nach DIN EN ISO/IEC 17025 akkreditiertes Prüflaboratorium. Die Akkreditierung gilt für die in der Urkunde aufgeführten Verfahren.
DAkkS Deutsche Akkreditierungsstelle D-PL-14559-03-01 D-PL-14559-03-02

Bad Bocklet 22 Feb 2017 / MEZ / Basfll

mblabor@basf.com

Certificate of Analysis

L+S No:	170216-0021-002	**L+S Code:**	0817356 / L
Product name:	DHA Algal Oil / Algenöl		
Description:	DH 5751, Blome 93419		
Your Order No:	4915012499		
Order dated:	15 Feb 2017	**Sample receipt:**	16 Feb 2017
Start of test:	17 Feb 2017	**End of test:**	22 Feb 2017

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
coliform bacteria, quantitative	L+S SOP 9.008		not detected / g DIN EN ISO 4831, mod.
Escherichia coli, qualitative	L+S SOP 9.009		not detected / g DIN EN ISO 16649, mod.
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / g DIN EN ISO 21528
total viable count, aerobic mesophilic 30°C	*L 00.00 - 88/2 mod.		< 10 CFU / g DIN EN ISO 4833-2
yeasts, quantitative	*L 01.00 - 37, mod.		< 10 CFU / g DIN EN ISO 21527
Salmonella sp., qualitative	*L 00.00 - 20		not detected / 25 g DIN EN ISO 6579
molds, quantitative	*L 01.00 - 37, mod.		< 10 CFU / g DIN EN ISO 21527
koagulase-positive Staphylokokken, qualitativ	L+S SOP 9.014		not detected / g DIN EN ISO 6888-1, mod.
Pseudomonas aeruginosa, qualitativ	L+S SOP 9.035		not detected / g DIN EN ISO 13720, mod.

LS|AG

L+S No 170216-0021-002 | **L+S Code** 0817356 / L |
Product name DHA Algal Oil / Algenöl

22. FEB. 2017

Dr Christian Arndt
Head of Department

SGS

SGS Germany GmbH Rödingsmarkt 16 20459 Hamburg

BASF Personal Care and Nutrition GmbH
Robert-Hansen-Straße 1
89257 Illertissen

Test Report 3264049
Order No. 4063689
Customer No. 10078225

Mandy Elias
Phone +49 40-30101-680
Fax +49 40-30101-943
mandy.elias@sgs.com

Agriculture, Food

SGS Germany GmbH
Rödingsmarkt 16
20459 Hamburg

DAkkS
Deutsche
Akkreditierungsstelle
D-PL-11020-04-01

Hamburg, 20.02.2017

Your order/project: .
Your purchase order number: 4935280662
Your purchase order date: 15.02.2017

General Information:

Sample No.:	170169208
Sample:	DHA Algal Oil DH 5751 Proben Nr.93419 15.02.2017
Date of receipt:	16.02.2017
Testing period (begin / end):	16.02.2017 / 17.02.2017
Packaging:	Plastic can
Quantity:	73g

Test Results:

Parameter	Method	Lab	Unit	Result	Limit of quantification	Requirements
Special analyses:						
Glycidylester det. as free Glycidol	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	< 10	10	
Sum free 2-MCPD, 2-MCPDester, det. as free 2-MCPD	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	12	10	
Sum free 3-MCPD, 3-MCPDester, det. as free 3-MCPD	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	285	10	

The laboratory sites of the SGS group Germany according to the abbreviations mentioned above are listed at http://www.institut-fresenius.de/filestore/89/laborstandortkuerzelsgs2.pdf.

SGS Germany

i.V. Ingrid Bujara / i.V. Dr. Sven-Erik Knopp / i.V. Claudia Koch / i.V. Lars Rückborn
i.A. Catherine Herzog / i.A. Heike Höfelmeier
/ i.A. Mandy Elias (Customer Service Consultants)

BASF

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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5752**
Production date	**2017-01-18**
Date of analysis	**2017-01-27 to 2017-02-22**

Specification Parameter and Further Tests

Results

Specification Parameter	Unit	Specification limit	Test result	Test method
Acid value	mg KOH/g	≤ 0.5	0.04	ISO 660
Peroxide value	meq O2/kg	≤ 4.0	0.5	ISO 3960
Unsaponifiable matter	%	≤ 35	0.8	PhEur 2.5.7
Moisture (Karl Fischer)	%	≤ 0.05	<0.01	DGF C-III 13a
Fatty acid C22:6 DHA as triglyceride	mg/g	≥ 380	394	PhEur 2.4.29
Trans fatty acids	area-%	≤ 1.0	0.1	IA-005057 *
Total tocopherols	mg/kg	not specified	2705	DIN EN ISO 9936 mod.
Anisidine value	-	≤ 15	1.9	DIN EN ISO 6885
Iron (Fe)	mg/kg	≤ 0.2	<0.1	DIN EN ISO 8294
Copper (Cu)	mg/kg	≤ 0.05	<0.01	DIN EN ISO 8294
Further Tests				
Free fatty acids	%	not specified	0.02	AOCS Ca 5a-40
Colour Gardner	-	not specified	5.5	DGF C-IV 4c
Ash (600°C)	%	not specified	0.0	DGF-C-III 10

* internal test method (GC-FID)

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen .

Dr. Edith von Kries
QC Manager

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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5752**
Production date	**2017-01-18**
Date of analysis	**2017-02-01**

Tocopherol Assay and Tocopherol Composition

Test method DIN EN ISO 9936 mod.

Results

Tocopherols	in mg/kg
alpha-tocopherol	432
beta-tocopherol	50
gamma-tocopherol	1592
delta-tocopherol	631
total tocopherols	2705

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

BASF
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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5752**
Production date	**2017-01-18**
Date of analysis	**2017-02-17**

Sterol Assay and Sterol Composition

Test method IA-000014 mod. (GC-FID)

Results

Total Sterols 0.2 weight-%

Sterol Isomer	Area-%
Cholestanol	<0.1
Cholesterol	9.0
Brassicasterol	4.3
24-Methylencholesterol	2.6
Campesterol	3.0
Campestanol	<0.1
Stigmasterol	15.5
D7-Campersterol	4.5
D5,23-Stigmastadienol	0.9
Clerosterol	13.4
Beta-Sitosterol	18.1
Sitostanol	<0.1
D5-Avenasterol	5.3
D5,24-Stigmastadienol	7.2
D7-Stigmastenol	12.5
D7-Avenasterol	4.0

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

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Analytical Report

Product	**DHA Algal Oil** **DHA-rich oil from the microalgae Schizochytrium sp.**
Lot no.	**DH5752**
Production date	**2017-01-18**
Date of analysis	**2017-02-17**

Fatty Acid Composition

Test method PhEur 2.4.29 (GC-FID)

Units all values expressed in area-%

Myristic acid C14:0	9.6
Palmitic acid C16:0	18.5
Palmitoleic acid C16:1 c9	6.8
Stearic acid C18:0	0.7
Oleic acid C18:1 c9	1.7
C18:1 total (oleic and cis-vaccenic acid)	10.7
Linoleic acid C18:2 c9,c12 n6	0.5
Alpha-linolenic acid C18:3 c9,c12,c15 n3	0.2
Stearidonic acid C18:4 c6,c9,c12,c15 n3	0.3
Arachidic acid C20:0	<0.1
C20:1 sum	<0.1
Arachidonic acid C20:4 n6	0.3
Eicosapentaenoic acid C20:5 n3	1.5
Heneicosapentaenoic acid C21:5 c18 n3	<0.1
Behenic acid C22:0	<0.1
Cetoleic acid C22:1 c11	<0.1
Erucic acid C22:1 c13	not detected
Docosapentaenoic acid C22:5 c16 n6	7.5
Docosapentaenoic acid C22:5 c19 n3	0.3
Docosahexaenoic acid C22:6 n3	42.2
Lignoceric acid C24:0	<0.1
Nervonic acid C24:1 c15	0.1
Trans fatty acids	0.1

Illertissen, 2017-03-14
BASF Personal Care and Nutrition GmbH
Location Illertissen

Dr. Edith von Kries
QC Manager

eurofins
WEJ Contaminants

Eurofins WEJ Contaminants GmbH
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BASF Personal Care and Nutrition GmbH
-Standort Illertissen-
Postfach 10 63
89251 Illertissen

Person in charge Ms D. Zarthe - 2907
Client support Ms D. Zarthe - 2907

Report date 20.02.2017

Analytical report: AR-17-JC-029173-02

This report replaces report number: AR-17-JC-029173-01

Sample Code 706-2017-00640084

Reference	DHA Algal Oil DH 5752
Client Sample Code	93418
Purchase Order Code	4935285868
Client contract reference	Rahmenbestell-Nr. 4935285868
Number	1
Amount	79 g
Reception temperature	room temperature
Ordered by	Qualitätskontrolle
Submitted by	Frau Edith von Kries
Sender	DHL
Reception date time	16.02.2017
Packaging	plastic container with plastic closure
Start/end of analyses	16.02.2017 / 20.02.2017

TEST RESULTS

Physical-chemical Analysis

JJ04T Phthalate + DEHA (#)

Method: Internal method, CON-PV 00629, GC-MS

Diethyl hexyl phthalate (DEHP)	<1	* mg/kg
Dimethyl phthalate (DMP)	<1	* mg/kg
Diethyl phthalate (DEP)	<1	* mg/kg
Dibutyl phthalate (DBP)	<0.3	** mg/kg
Di-isobutyl phthalate (DiBP)	<0.3	** mg/kg
Benzyl butyl phthalate (BBP)	<1	* mg/kg
Dioctyl phthalate (D-n-OP)	<1	* mg/kg
DINCH	<5	* mg/kg
Diisononylphthalate (DINP)	<5	* mg/kg
Diisodecylphthalate (DIDP)	<5	* mg/kg
Diethylhexyl adipate (DEHA)	<1	* mg/kg
Triisobutyl phosphate	<1	* mg/kg
Acetyltributylcitrat (ATBC)	<1	* mg/kg

* = Below indicated quantification level

** = Below indicated detection level

(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test.

Result +/- expanded measurement uncertainty (95%; k=2)

Analytical report: AR-17-JC-029173-02
Sample Code 706-2017-00640084

eurofins

WEJ Contaminants

This report replaces report number: AR-17-JC-029173-01

Signature

Analytical Service Manager (Doris Zarthe)

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Eurofins WEJ Contaminants · Neuländer Kamp 1 · D-21079 Hamburg

BASF Personal Care and Nutrition GmbH
-Standort Illertissen-
Postfach 10 63
89251 Illertissen

Person in charge Ms D. Zarthe - 2907
Client support Ms D. Zarthe - 2907

Report date 27.02.2017

Analytical report: AR-17-JC-032949-02

This report replaces report number: AR-17-JC-032949-01

Sample Code 706-2017-00640083

Reference	DHA Algal Oil DH 5752
Client Sample Code	93418
Purchase Order Code	4935285868
Client contract reference	Rahmenbestell-Nr. 4935285868
Number	1
Amount	160 g
Reception temperature	room temperature
Ordered by	Qualitätskontrolle
Submitted by	Frau Edith von Kries
Sender	DHL
Reception date time	16.02.2017
Packaging	plastic container with plastic closure
Start/end of analyses	16.02.2017 / 27.02.2017

TEST RESULTS

Physical-chemical Analysis

J1001	**Sample preparation (#)**			
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)			
JCM03	**Lead (Pb) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Lead (Pb)		<0.02	*	mg/kg
J8308	**Cadmium (Cd) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Cadmium (Cd)		<0.01	*	mg/kg
JCHG2	**Mercury (Hg) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Mercury (Hg)		<0.005	*	mg/kg
J8312	**Arsenic (As) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Arsenic (As)		<0.1	*	mg/kg
J1042	**Copper (Cu) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Copper (Cu)		<0.1	*	mg/kg
J1043	**Iron (Fe) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Iron (Fe)		<0.5	*	mg/kg

This report replaces report number: AR-17-JC-032949-01

JJ0CG	**Chromium (Cr) (#)**			
Method:	DIN EN ISO 17294-2-E29, CON-PV 00857, ICP-MS			
Chromium (Cr)		<0.05	*	mg/kg
J1049	**Nickel (Ni) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Nickel (Ni)		<0.1	*	mg/kg
J1047	**Manganese (Mn) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Manganese (Mn)		<0.1	*	mg/kg
J1050	**Phosphorus (P) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Phosphorus (P)		<3	*	mg/kg
J1054	**Sulphur (S) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Sulphur total (S)		<2	*	mg/kg
J1056	**Silicon (Si) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Silicon (Si)		28		mg/kg
		± 6		mg/kg
J1011	**Molybdenum (Mo) (#)**			
Method:	§64 LFGB L00.00-19/3, CON-PV 00508, GF-AAS			
Molybdenum (Mo)		<0.2	*	mg/kg

GF08T **MS/MS ~ PCDD/F ~ 17 congeneres ~ food / feed**

Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

2,3,7,8-TetraCDD	< 0.030	pg/g
1,2,3,7,8-PentaCDD	< 0.040	pg/g
1,2,3,4,7,8-HexaCDD	< 0.060	pg/g
1,2,3,6,7,8-HexaCDD	< 0.082	pg/g
1,2,3,7,8,9-HexaCDD	< 0.078	pg/g
1,2,3,4,6,7,8-HeptaCDD	< 0.13	pg/g
OctaCDD	< 0.92	pg/g
2,3,7,8-TetraCDF	< 0.24	pg/g
1,2,3,7,8-PentaCDF	< 0.057	pg/g
2,3,4,7,8-PentaCDF	< 0.089	pg/g
1,2,3,4,7,8-HexaCDF	< 0.094	pg/g
1,2,3,6,7,8-HexaCDF	< 0.086	pg/g
1,2,3,7,8,9-HexaCDF	< 0.063	pg/g
2,3,4,6,7,8-HexaCDF	< 0.078	pg/g
1,2,3,4,6,7,8-HeptaCDF	< 0.089	pg/g
1,2,3,4,7,8,9-HeptaCDF	< 0.062	pg/g
OctaCDF	< 0.19	pg/g
WHO(2005)-PCDD/F TEQ (upper-bound)	0.179	pg/g

GF09T **MS/MS ~ PCB ~ dioxin-like / 12 WHO ~ food / feed**

Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS

Subcontracted to a Eurofins laboratory accredited for this test.

PCB 77	< 2.9	pg/g
PCB 81	< 0.43	pg/g
PCB 105	< 6.2	pg/g
PCB 114	< 0.84	pg/g
PCB 118	< 22	pg/g
PCB 123	< 0.63	pg/g
PCB 126	< 0.40	pg/g

This report replaces report number: AR-17-JC-032949-01

PCB 156		< 3.5	pg/g
PCB 157		< 0.65	pg/g
PCB 167		< 1.7	pg/g
PCB 169		< 1.9	pg/g
PCB 189		< 0.63	pg/g
WHO(2005)-PCB TEQ (upper-bound)		0.0982	pg/g

GF004 WHO-PCDD/F+PCB TEQ
Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, Calculation
Subcontracted to a Eurofins laboratory accredited for this test.

WHO(2005)-PCDD/F+PCB TEQ (upper-bound)		0.277	pg/g

GF10T MS/MS ~ PCB ~ 6 ndl ~ food / feed
Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS DF 100, GC-MS/MS
Subcontracted to a Eurofins laboratory accredited for this test.

PCB 28		< 0.16	ng/g
PCB 52		< 0.16	ng/g
PCB 101		< 0.16	ng/g
PCB 138		< 0.16	ng/g
PCB 153		< 0.16	ng/g
PCB 180		< 0.16	ng/g
Total 6 ndl-PCB (upper-bound)		0.951	ng/g

JCP01 Preparation PAH (Caffeine complexation) (#)
Method: Internal method, CON-PV 01176, Extraction

JC00U PAH 4 (#)
Method: Internal method, CON-PV 01176, GC-MS

Benzo(a)anthracene		<0.5	* µg/kg
Benzo(a)pyrene		<0.5	* µg/kg
Benzo(b)fluoranthene		<0.5	* µg/kg
Chrysene		<0.5	* µg/kg
Sum PAH 4	Inapplicable		

JJL3K Shellfish Poisons ASP, PSP, Okadaic acid, Dinophysistoxins
Method: BVL L 12.03/04-1/3/4, , LC-MS/MS
Subcontracted to an external laboratory

Amnesic Shellfish Poison, Domoic acid		<1	* mg/kg
Okadaic acid		<5	* µg/kg
Paralytic Shellfish Poison, Saxitoxin		<20	* µg/kg
DTX-1		<5	* µg/kg

A0428 Aflatoxins B1, B2, G1, G2 (Baby food, dietary food) (#)
Method: EN 15851, mod., CON-PV 00855, IAC-LC-FLD

Aflatoxin B1		<0.01	* µg/kg
Aflatoxin B2		<0.01	* µg/kg
Aflatoxin G1		<0.01	* µg/kg
Aflatoxin G2		<0.01	* µg/kg
Sum of all positive Aflatoxins		<0.04	* µg/kg

* = Below indicated quantification level
(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test.
Result +/- expanded measurement uncertainty (95%, k=2)

Signature

Analytical Service Manager (Doris Zarthe)

SGS

SGS Germany GmbH Rödingsmarkt 16 20459 Hamburg

BASF Personal Care and Nutrition GmbH
Robert-Hansen-Straße 1
89257 Illertissen

Test Report 3264048
Order No. 4063689
Customer No. 10078225

Mandy Elias
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mandy.elias@sgs.com

Agriculture, Food

SGS Germany GmbH
Rödingsmarkt 16
20459 Hamburg

DAkkS Deutsche Akkreditierungsstelle D-PL-11020-04-01

Hamburg, 20.02.2017

Your order/project: .
Your purchase order number: 4935280662
Your purchase order date: 15.02.2017

General Information:

Sample No.:	170169207
Sample:	DHA Algal Oil DH 5752 Proben Nr.93418 15.02.2017
Date of receipt:	16.02.2017
Testing period (begin / end):	16.02.2017 / 17.02.2017
Packaging:	Plastic can
Quantity:	57g

Test Results:

Parameter	Method	Lab	Unit	Result	Limit of quantification	Requirements
Special analyses:						
Glycidylester det. as free Glycidol	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	< 10	10	
Sum free 2-MCPD, 2-MCPDester, det. as free 2-MCPD	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	< 10	10	
Sum free 3-MCPD, 3-MCPDester, det. as free 3-MCPD	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	129	10	

The laboratory sites of the SGS group Germany according to the abbreviations mentioned above are listed at http://www.institut-fresenius.de/filestore/89/laborstandortkuerzelsgs2.pdf.

SGS Germany

.....
i.V. Ingrid Bujara / i.V. Dr. Sven-Erik Knopp / i.V. Claudia Koch / i.V. Lars Rückborn
i.A. Catherine Herzog / i.A. Heike Höfelmeier
/ i.A. Mandy Elias (Customer Service Consultants)

LS|AG

Labor L+S AG Mangelsfeld 4, 5, 6 | 97708 Bad Bocklet-Großenbrach | Germany
BASF Personal Care and Nutrition GmbH
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Robert-Hansen-Straße 1
89257 Illertissen

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E-Mail: labor@labor-ls.de Internet: www.labor-ls.de
Akkreditiert nach ISO / IEC 17025
Durch die DAkkS Deutsche Akkreditierungsstelle GmbH nach DIN EN ISO/IEC 17025 akkreditiertes Prüflaboratorium.
Die Akkreditierung gilt für die in der Urkunde aufgeführten Verfahren.
DAkkS Deutsche Akkreditierungsstelle
D-PL-14159-01-01
D-PL-14159-01-02

Bad Bocklet 22 Feb 2017 / MEZ / Basfil

mblabor@basf.com

Certificate of Analysis

L+S No:	170216-0021-001	**L+S Code:**	0817355 / L
Product name:	DHA Algal Oil / Algenöl		
Description:	DH 5752, Blome 93418		
Your Order No:	4915012499		
Order dated:	15 Feb 2017	**Sample receipt:**	16 Feb 2017
Start of test:	17 Feb 2017	**End of test:**	22 Feb 2017

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
coliform bacteria, quantitative	L+S SOP 9.008		not detected / g DIN EN ISO 4831, mod.
Escherichia coli, qualitative	L+S SOP 9.009		not detected / g DIN EN ISO 16649, mod.
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / g DIN EN ISO 21528
total viable count, aerobic mesophilic 30°C	*L 00.00 - 88/2 mod.		< 10 CFU / g DIN EN ISO 4833-2
yeasts, quantitative	*L 01.00 - 37, mod.		< 10 CFU / g DIN EN ISO 21527
Salmonella sp., qualitative	*L 00.00 - 20		not detected / 25 g DIN EN ISO 6579
molds, quantitative	*L 01.00 - 37, mod.		< 10 CFU / g DIN EN ISO 21527
koagulase-positive Staphylokokken, qualitativ	L+S SOP 9.014		not detected / g DIN EN ISO 6888-1, mod.
Pseudomonas aeruginosa, qualitativ	L+S SOP 9.035		not detected / g DIN EN ISO 13720, mod.

LS|AG

L+S No 170216-0021-001 | **L+S Code** 0817355 / L |
Product name DHA Algal Oil / Algenöl

22. FEB. 2017

Dr Christian Arndt
Head of Department

Modena (Italy), li 01/03/2017 Page 1 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE **17B12440**

Analysis beginning date **16/02/2017**

Registration date **16/02/2017**

Description provided by Customer: DHA ALGAL OIL DH 5752 - SAMPLE-NO.: 93418 - SAMPLE ARRIVED ON 16/02/2017- THE SAMPLE HAS BEEN TAKEN BY THE CUSTOMER. THE TRANSPORT HAS BEEN MADE BY CARRIER.
Sample Condition on Receipt: Room temperature

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
QuEChERS Basic - Nuts, oleaginous seeds and oil BIO								
Flonicamid (LCMS)	< LQ			mg/kg	0.003		* lcms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Flonicamid metabolite: TFNA	< LQ			mg/kg	0.003		* lcms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Flonicamid metabolite: TFNG	< LQ			mg/kg	0.003		* lcms-Q 2014 Rev.0 - LC-MS/MS	23/02/2017
Abamectin	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acetamiprid	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acetochlor	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Acibenzolar-S-methyl	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Aclonifen	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Acrinathrin	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Alachlor	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Aldrin	< LQ			mg/kg	0.003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Dieldrin	< LQ			mg/kg	0.003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Aldrin and dieldrin, sum expressed in dieldrin [414]	< LQ			mg/kg	0.003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Ametryn	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine-desethyl	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Atrazine-desisopropyl	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azadirachtin-A	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azinphos-ethyl	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azinphos-methyl	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Azoxystrobin	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Benalaxyl, sum of isomers including Benalaxyl-M	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Benfluralin	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Benomyl, Carbendazim sum expressed as Carbendazim [414]	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbendazim	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

Continued...

neotron S.p.A.
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB. N°0026

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Benthiavalicarb-isopropyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Bifenazate	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Bifenox	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Bifenthrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bitertanol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Boscalid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Bromophos-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromophos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromopropylate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bromuconazole, sum of cis- and trans-isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Bupirimate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Buprofezin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Butylate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cadusaphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbaryl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran (including any carbofuran generated from carbosulfan, benfuracarb or furathiocarb)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran-3-hydroxy	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Carbofuran and Carbofuran-3-hydroxy, sum expressed as Carbofuran [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlordane cis	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane oxi	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane trans	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlordane sum of cis and trans-isomers [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorfenvinphos, sum of E and Z isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlormephos	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Chlorotoluron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlorpropham	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorpyriphos ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorpyriphos methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Chlorsulfuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Chlorthal dimethyl	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Clofentezine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel

ACCREDIA
LAB. N°0826
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Modena (Italy), li 01/03/2017 Page 3 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Chlorantraniliprole (DPX E-2Y45)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Coumaphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyanazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyazofamide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cycloate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cycloxydim	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyfluthrin e Cyfluthrin beta, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cyhalothrin lambda, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cymoxanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cypermethrin, including other mixtures of constituent isomers (sum of isomers)	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Cyproconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Cyprodinil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
o,p'-DDD	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDD	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
o,p'-DDE	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDE	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
o,p'-DDT	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
p,p'-DDT	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
DDT, sum, of pp'-DDT, op'-DDT, pp'-DDE, pp'DDD expressed as DDT [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Deltamethrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Diazinon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichlobenil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Dichlofluanid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichlofluanid and DMSA, sum expressed as dichlofluanid [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethyl-sulfanilide (DMSA)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dichloran	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Dichlorvos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dietofencarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Difenoconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Diflubenzuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB N°0026
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Diflufenican	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethenamid, sum of isomers including dimethenamid-P	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethoate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Omethoate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethoate and Omethoato, sum expressed as dimethoate [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethomorph, sum of isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Ditalimfos	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Diuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dodine	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Emamectin benzoate B1a, value expressed as emamectin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Endosulfan alpha	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulfan beta	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulfan sulphate	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endosulphan, sum of alpha and beta isomers and of endosulfan sulphate, expressed as endosulfan [414]	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Endrin	< LQ			mg/kg	0,003		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Epoxyconazol	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
EPTC	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Esfenvalerate and Fenvalerate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethofumesate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Ethoprophos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Etofenprox	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Etoxazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Famoxadone	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenamidone	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenamiphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenamiphos-sulfoxide	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fenamiphos-sulfone	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB. N°0076

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Fenamiphos, fenamiphos-sulfone, fenamiphos-sulfoxide, sum expressed as fenamiphos [414]	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fenarimol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenazaquin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenbuconazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos-oxon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenchlorphos and fenchlorphos-oxon sum expressed as fenchlorphos [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenhexamid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenitrothion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenoxaprop-p-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenoxycarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenpropathrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenpropidin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenpropimorph	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fenpyroximate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-oxon-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fenthion, fenthion-oxon, fenthion-oxon-sulfone, fenthion-oxon-sulfoxide, fenthion-sulfone, fenthion-sulfoxide, sum expressed as fenthion [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Flazasulfuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Flucythrinate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fludioxonil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Flufenacet	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Flufenoxuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fluopicolide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fluquinconazole	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Flusilazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuesmonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB N°0429

Modena (Italy), li 01/03/2017 Page 6 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Flutriafol	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Fluvalinate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Fonofos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Formothion	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Fosthiazate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
HCH alpha	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH beta	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH delta	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH epsilon	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
HCH, sum of HCH alpha, beta, delta and epsilon [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor Epoxide cis	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor Epoxide trans	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptachlor, Heptachlor Epoxide cis and Epoxide trans sum expressed as Heptachlor [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Heptenophos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Hexachlorobenzene	< LQ			mg/kg	0,002		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Hexaconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Hexythiazox	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Imazalil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Imidacloprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Indoxacarb, sum of R and S isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Iodofenphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Iprodione	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Iprovalicarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Isofenphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Isofenphos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Isoprothiolane	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Isoproturon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Kresoxim-methyl	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Lindane	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Lindane, sum of HCH isomers included Lindane [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

Continued...

neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB N°0024

Modena (Italy), li 01/03/2017 Page 7 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Linuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Lufenuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malaoxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malathion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Malathion and Malaoxon sum expressed as Malathion [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mandipropamid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mecarbam	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mepanipyrim	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metalaxyl, sum of isomers including Metalaxyl-M	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metazachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Methidathion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Methiocarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methiocarb, methiocarb sulfone and methiocarb sulfoxide, sum expressed as Methiocarb [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methomyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiodicarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methomyl and Thiordicarb sum expressed as Methomyl [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Methoxychlor	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Methoxyfenozide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Metolachlor, sum of isomers including S-metolachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metrafenone	< LQ			mg/kg	0,010		* icms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Metribuzin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Metsulfuron-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Mevinphos, sum of cis- and trans-isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Molinate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Monuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
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ACCREDIA
LAB. N°0025

Modena (Italy), li 01/03/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Myclobutanil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Napropamide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Oxadiazon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Oxadixyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Oxyfluorfen	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paclobutrazol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paraoxon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Paraoxon-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion and Paraoxon sum expressed as Parathion [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Parathion-methyl and Paraoxon-methyl sum expressed as Parathion-methyl [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Penconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pencycuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pendimethalin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Permethrin, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Perthane	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Phenmedipham	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phenthoate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Phorate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phorate, phorate-oxon, phorate-sulfone and phorate-sulfoxide, sum expressed as phorate [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosalone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosmet and phosmet-oxon expressed as phosmet [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Phosphamidon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Picoxystrobin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Piperonyl butoxide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017

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ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
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ACCREDIA
LAB. N°0828
Signatory of EA, IAF and ILAC Mutual Recognition Agreement

Modena (Italy), li 01/03/2017 Page 9 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Pirimicarb (Pirimor)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimicarb-desmethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimicarb and pirimicarb-desmethyl, sum expressed as pirimicarb [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pirimiphos-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Pirimiphos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Prochloraz	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Procymidone	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Profenofos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Prometryn	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propachlor	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propaquizafop	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propargite	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propiconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propoxur	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Propyzamide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Proquinazid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyraclostrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyrazophos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyrethrins: pyrethrin I and II, cinerin I and II, jasmolin I and II, sum (low limit)	< LQ			mg/kg	0,010		+ lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Pyridaben	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Pyrimethanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Pyriproxyfen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Quinalphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Quinoxifen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Quintozene	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Pentachloroaniline	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Quintozene and pentacloroanilin, sum expressed as quintozene [414]	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

Continued...

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ANALYTICAL AND TECHNICAL SERVICES

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ACCREDIA
LAB. N°0076

Modena (Italy), li 01/03/2017 Page 10 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Rotenone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Simazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spinosad, sum of spinosyn A and spinosyn D	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirodiclofen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirotetramat	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Spirotetramat enol	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat enol-glucoside	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat ketohydroxy	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat monohydroxy	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spirotetramat and its metabilites (enol, enol-glucoside, ketohydroxy, monohydroxy) sum as spirotetramat [414]	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	01/03/2017
Spiroxamine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Sulfallate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Sulfotep	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Tebuconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tebufenozide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tebufenpyrad	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Teflubenzuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tefluthrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Terbuthylazine	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Tetrachlorvinphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tetraconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tetradifon	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/RVC-G2) rev5 2015 - GC-ECD	24/02/2017
Tetramethrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Thiabendazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiacloprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiamethoxam	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Thiobencarbe	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Thionazin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

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ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
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QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
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ACCREDIA
LAB N°0026

Modena (Italy), li 01/03/2017 Page 11 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSIS ENDING DATE
Thiophanate-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tolclofos-methyl	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Tolylfluanid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Dimethylaminosulphotoluidide (DMST)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tolylfluanid and DMST, sum expressed as tolylfluanid [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triadimefon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triadimenol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triadimefon and Triadimenol, sum [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triallate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Di-allate (sum of isomers)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triallate and Diallate sum expressed as Triallate [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	27/02/2017
Triazophos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trichlorfon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Tricyclazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trifloxystrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Triflumuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Trifluralin	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017
Triticonazole	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	27/02/2017
Vamidothion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017
Vinchlozolin	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	24/02/2017

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ANALYTICAL AND TECHNICAL SERVICES

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Modena (Italy), li 01/03/2017 Page 12 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17B12440-In-0

SAMPLE 17B12440

Analysis beginning date 16/02/2017

Registration date 16/02/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Zoxamide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	01/03/2017

END TEST REPORT

Notes and method reference:
< LQ: = lower than Quantification Limit. Please note that results expressed as '<LQ' may not indicate the absence of the searched parameters in the sample.
U: the reported uncertainty is the expanded uncertainty calculated using a coverage factor equal to 2 which gives a reliability of approximately 95%. For microbiological detections it is reported either the lower and the upper bounds of the confidence interval with a probability of 95% K=2 or the confidence interval itself.
Results coming from microbiological tests are calculated according to the Standard ISO 7218:2007/Amd 1:2013. If the results are reported as <4 (CFU/ml) or <40 (CFU/g), this means that the microorganisms are present in the sample but in amounts less than 4 CFU/ml or 40 CFU/g respectively.
LQ: Quantification Limit. It is the lowest analyte concentration which can be detected at an acceptable precision (repeatability) and accuracy, under well defined conditions.
LD: Detection Limit. It is the lowest analyte concentration which can be detected but not necessarily quantified, under well defined conditions.
Conformity evaluation: values not complying with laws, decrees, national and EU regulations or specifications supplied by the customer are evaluated case by case, also taking into consideration the uncertainty of measure for each single test and the regulations on rounding-off of values, and pointed out when considered as "non conform".
Rec %: Recovery % "+" means that the recovery has been applied to the result. The numeric results between brackets (..) after the espression <LQ are purely indicative of traces that cannot be exactly quantified.
Methods marked with an asterisk (*) are not accredited by ACCREDIA (UNI CEI EN ISO/IEC 17025)

NOTES OF PARAMETERS:
[414]: The sum is calculated through the lower bound criterion.

TEST REPORT VALID FOR ALL LEGAL PURPOSES (Italian R.D. 1-3-1928 n°842 (article 16), – Italian Law 19-7-1957 n°679 articles 16 and 18, Italian Ministerial Decree 25-3-1986).
Test Report issued according to the 17025:2005 Standard
DATA and SAMPLE STORAGE: Raw data, chromatographic paths and instrumental reports are stored for 5 years. One control sample is stored for 2 months.
Data expressed in this test report refer only to the sample tested in the laboratory. The description or any other reference concerning the sample are declared by the customer. This Test Report cannot be reproduced except in full. Partial reproductions must be authorized in writing by our laboratory.

LABORATORY MANAGER: DR. GIAN CARLO GATTI - MEMBER OF AOAC N. VM 90231001 - EURCHEM
Approved by Analysis Manager - laboratory LMIA-pest

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GMP Pharmaceutical Laboratories Authorized by AIFA Italian Medicine Agency n° aM- 55/2015.
Laboratorio Qualificato D.M. 26-2-87 Art. 4 - Legge 46/82 per la Ricerca Applicata e Innovazione Tecnologica.
Regione Emilia Romagna - AUTORIZZAZIONE Autocontrollo N° 008/MO/008
BNN-Monitoring Fruit and Vegetables Approved Laboratory
I-Monitoring EDEKA AG Fruit and Vegetables Registered Laboratory

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Body of Certificate

Please note that the certificates of analysis are also conveniently available online and around the clock at www.worldaccount.basf.com

2017-09-15
Head of Q
juergen.dremel@basf.com
+49 7303 13-372
Reg. 20170915104540

Inspection Certificate 3.1 according to EN 10204

DHA Algal Oil

Material 50375580

25KG Steel Drums

Lot 0016888247

Characteristic Method	Unit	Value	Lower Limit	Upper Limit
APPEARANCE AX-001001		PASS		
ACID VALUE MG KOH/G ISO 660		0,1	0,0	0,5
PEROXIDE VALUE MEQ O2/KG ISO 3960		< 0,1	0,0	4,0
UNSAPONIFIABLE MATTER PhEur 2.5.7	%	1,6	0,0	3,5
WATER CONTENT, KARL FISCHER DGF C-III 13a	%	0,02	0,00	0,05
FATTY ACID C22:6 (DHA) (AS TG) PhEur 2.4.29	mg/g	403	380	
FATTY ACID TRANS, SUM IA-001057	%(a)	0,1		1,0
TOTAL TOCOPHEROLS IA-005034	mg/kg	2993		
ANISIDINE VALUE DIN EN ISO 6885		3	0	15
IRON DIN EN ISO 8294	mg/kg	< 0,1	0,0	0,2
COPPER DIN EN ISO 8294	mg/kg	< 0,05	0,00	0,05

Released by J.Dremel

Production date (dd.mm.yyyy) 16.03.2017

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.

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2017-09-15
Head of Q
juergen.dremel@basf.com
+49 7303 13-372
Reg. 20170915104540

Inspection Certificate 3.1 according to EN 10204

DHA Algal Oil

Material 50375580

25KG Steel Drums

Lot 0016888247

Release date	13.04.2017
Retest date / Best Before date	16.03.2019

BASF Personal Care & Nutrition GmbH
89257 Illertissen, Germany

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WEJ Contaminants

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http://www.eurofins.de/wej-contaminants.aspx

Eurofins WEJ Contaminants · Neuländer Kamp 1 · D-21079 Hamburg

BASF Personal Care and Nutrition GmbH
-Standort Illertissen-
Postfach 10 63
89251 Illertissen

Person in charge Ms D. Zarthe - 2907
Client support Ms D. Zarthe - 2907

Report date 30.03.2017

Analytical report: AR-17-JC-051960-01

Sample Code 706-2017-00661020

Reference	Algenöl
Client Sample Code	10998331 ROLL
Purchase Order Code	4935285868
Client contract reference	Rahmenbestell-Nr. 4935285868
Lot-no.	0016888247
Number	1
Amount	470 g
Reception temperature	room temperature
Ordered by	Frau Edith von Kries
Submitted by	Frau Edith von Kries
Sender	DHL
Reception date time	23.03.2017
Packaging	plastic container with plastic closure
Start/end of analyses	23.03.2017 / 28.03.2017

TEST RESULTS

Physical-chemical Analysis

J1001	**Sample preparation (#)**			
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)			
J8306	**Lead (Pb) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Lead (Pb)		<0.05	*	mg/kg
J8308	**Cadmium (Cd) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Cadmium (Cd)		<0.01	*	mg/kg
JCHG2	**Mercury (Hg) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Mercury (Hg)		<0.005	*	mg/kg
J8312	**Arsenic (As) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Arsenic (As)		<0.1	*	mg/kg

GFL01 polychlorinated dibenzodioxins and -furans (17 PCDD/F): vegetable/animal oil and fats in food

Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS NG 100, GC-MS/MS
Subcontracted to a Eurofins laboratory accredited for this test.

2,3,7,8-TetraCDD	< 0.060	*	pg/g
1,2,3,7,8-PentaCDD	< 0.079	*	pg/g
1,2,3,4,7,8-HexaCDD	< 0.12	*	pg/g
1,2,3,6,7,8-HexaCDD	< 0.16	*	pg/g
1,2,3,7,8,9-HexaCDD	< 0.15	*	pg/g
1,2,3,4,6,7,8-HeptaCDD	< 0.25	*	pg/g
OctaCDD	< 1.8	*	pg/g
2,3,7,8-TetraCDF	< 0.16	*	pg/g
1,2,3,7,8-PentaCDF	< 0.11	*	pg/g
2,3,4,7,8-PentaCDF	< 0.18	*	pg/g
1,2,3,4,7,8-HexaCDF	< 0.19	*	pg/g
1,2,3,6,7,8-HexaCDF	< 0.17	*	pg/g
1,2,3,7,8,9-HexaCDF	< 0.13	*	pg/g
2,3,4,6,7,8-HexaCDF	< 0.15	*	pg/g
1,2,3,4,6,7,8-HeptaCDF	< 0.18	*	pg/g
1,2,3,4,7,8,9-HeptaCDF	< 0.12	*	pg/g
OctaCDF	< 0.38	*	pg/g
WHO(2005)-PCDD/F TEQ (upper-bound)	0.324		pg/g

GFL07 polychlorinated biphenyls (12 WHO PCB + 6 ICES PCB): vegetable/animal oil and fats in food

Method: EC Reg 589/2014 (food) and EC Reg 709/2014 (feed), GLS NG 100, GC-MS/MS
Subcontracted to a Eurofins laboratory accredited for this test.

PCB 77	< 5.7	*	pg/g
PCB 81	< 0.85	*	pg/g
PCB 105	< 12	*	pg/g
PCB 114	< 1.7	*	pg/g
PCB 118	< 44	*	pg/g
PCB 123	< 1.3	*	pg/g
PCB 126	< 0.79	*	pg/g
PCB 156	< 6.9	*	pg/g
PCB 157	< 1.3	*	pg/g
PCB 167	< 3.5	*	pg/g
PCB 169	< 3.8	*	pg/g
PCB 189	< 1.3	*	pg/g
WHO(2005)-PCB TEQ (upper-bound)	0.195		pg/g
PCB 28	< 0.31	*	ng/g
PCB 52	< 0.31	*	ng/g
PCB 101	< 0.31	*	ng/g
PCB 138	< 0.31	*	ng/g
PCB 153	< 0.31	*	ng/g
PCB 180	< 0.31	*	ng/g
Total 6 ndl-PCB (upper-bound)	1.89		ng/g

GFTE1 TEQ-Totals WHO-PCDD/F and PCB

Method: Internal method, , Calculation
Subcontracted to a Eurofins laboratory accredited for this test.

WHO(2005)-PCDD/F+PCB TEQ (upper-bound)	0.519		pg/g

JCP01	**Preparation PAH (Caffeine complexation) (#)**		
Method:	Internal method, CON-PV 01176, Extraction		
JC00U	**PAH 4 (#)**		
Method:	Internal method, CON-PV 01176, GC-MS		
Benzo(a)anthracene		<0.5	* µg/kg
Benzo(a)pyrene		<0.5	* µg/kg
Benzo(b)fluoranthene		<0.5	* µg/kg
Chrysene		<0.5	* µg/kg
Sum PAH 4		Inapplicable	
A0428	**Aflatoxins B1, B2, G1, G2 (Baby food, dietary food) (#)**		
Method:	EN 15851, mod., CON-PV 00855, IAC-LC-FLD		
Aflatoxin B1		<0.01	* µg/kg
Aflatoxin B2		<0.01	* µg/kg
Aflatoxin G1		<0.01	* µg/kg
Aflatoxin G2		<0.01	* µg/kg
Sum of all positive Aflatoxins		<0.04	* µg/kg

* = Below indicated quantification level

(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test.

Result +/- expanded measurement uncertainty (95%; k=2)

Signature

Analytical Service Manager (Doris Zarthe)

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BASF Personal Care and Nutrition GmbH
-Standort Illertissen-
Postfach 10 63
89251 Illertissen

Person in charge Ms D. Zarthe - 2907
Client support Ms D. Zarthe - 2907

Report date 24.03.2017

Analytical report: AR-17-JC-048552-01

Sample Code 706-2017-00661021

Reference	Algenöl
Client Sample Code	10998331 ROLL
Purchase Order Code	4935285868
Client contract reference	Rahmenbestell-Nr. 4935285868
Lot-no.	0016888247
Number	1
Amount	74 g
Reception temperature	room temperature
Ordered by	Frau Edith von Kries
Submitted by	Frau Edith von Kries
Sender	DHL
Reception date time	23.03.2017
Packaging	plastic container with plastic closure
Start/end of analyses	23.03.2017 / 23.03.2017

TEST RESULTS

Physical-chemical Analysis

JJ04T Phthalate + DEHA (#)

Method: Internal method, CON-PV 00629, GC-MS

Diethyl hexyl phthalate (DEHP)	<1	* mg/kg
Dimethyl phthalate (DMP)	<1	* mg/kg
Diethyl phthalate (DEP)	<1	* mg/kg
Dibutyl phthalate (DBP)	<0.3	** mg/kg
Di-isobutyl phthalate (DiBP)	<0.3	** mg/kg
Benzyl butyl phthalate (BBP)	<1	* mg/kg
Dioctyl phthalate (D-n-OP)	<1	* mg/kg
DINCH	<50	* mg/kg
Diisononylphthalate (DINP)	<5	* mg/kg
Diisodecylphthalate (DIDP)	<50	* mg/kg
Diethylhexyl adipate (DEHA)	<1	* mg/kg
Triisobutyl phosphate	<1	* mg/kg
Acetyltributylcitrat (ATBC)	<1	* mg/kg

* = Below indicated quantification level

** = Below indicated detection level

(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test.

Result +/- expanded measurement uncertainty (95%; k=2)

Signature

Analytical Service Manager (Doris Zarthe)

SGS

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BASF Personal Care and Nutrition GmbH
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89257 Illertissen

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Auftrags Nr. 4104590
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Agriculture, Food

SGS Germany GmbH
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DAkkS Deutsche Akkreditierungsstelle D-PL-11020-04-01

Hamburg, den 28.03.2017

Ihr Auftrag/Projekt: .
Ihre Bestellnummer: 4935280662
Ihr Bestelldatum: 22.03.2017

Allgemeine Angaben:

Proben-Nr.:	170305321
Probe:	Algenöl 10998331 ROLL 0016888247 vom 21.03.2017
Probeneingangsdatum:	23.03.2017
Untersuchungsbeginn / -ende:	23.03.2017 / 28.03.2017
Verpackungsart:	Plastic bottle
Menge:	78g

Untersuchungsergebnisse:

Parameter	Methode	Lab	Einheit	Ergebnis	Bestimmungsgrenze	Anforderung
Spezielle Untersuchungen:						
Glycidylester, best. als freies Glycidol	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	< 10	10	
Summe freies 2-MCPD, 2-MCPDester, best. als freies 2-MCPD	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	38	10	
Summe freies 3-MCPD, 3-MCPDester, best. als freies 3-MCPD	SGS "3in1" Low LOQ, AOCS Cd 29b-13 mod., GC/MS	HH	µg/kg	436	10	

Die Laborstandorte der SGS Gruppe Deutschland und Schweiz gemäß den oben genannten Kürzeln sind aufgeführt unter http://www.institut-fresenius.de/filestore/89/laborstandortkuerzelsgs2.pdf.

SGS Germany

i.V. Ingrid Bujara / i.V. Dr. Sven-Erik Knopp / i.V. Claudia Koch / i.V. Lars Rückborn
/ i.A. Catherine Herzog / i.A. Heike Höfelmeier
/ i.A. Mandy Elias (Customer Service Consultants)

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Modena (Italy), li 07/04/2017 Page 1 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

Description provided by Customer: ALGAE OIL - 10998331 ROLL - 0016888247 - VOM 21.03.2017 - SAMPLE ARRIVED ON 23/03/2017- THE SAMPLE HAS BEEN TAKEN BY THE CUSTOMER. THE TRANSPORT HAS BEEN MADE BY CARRIER. Sample Condition on Receipt: Room temperature

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
QuEChERS Basic - Nuts, oleaginous seeds and oil BIO								
Flonicamid (LCMS)	< LQ			mg/kg	0,003		* lcms-Q 2014 Rev.0 - LC-MS/MS	03/04/2017
Flonicamid metabolite: TFNA	< LQ			mg/kg	0,003		* lcms-Q 2014 Rev.0 - LC-MS/MS	03/04/2017
Flonicamid metabolite: TFNG	< LQ			mg/kg	0,003		* lcms-Q 2014 Rev.0 - LC-MS/MS	03/04/2017
Abamectin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Acetamiprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Acetochlor	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Acibenzolar-S-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Aclonifen	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Acrinathrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Alachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Aldrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Dieldrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Aldrin and dieldrin, sum expressed in dieldrin [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Ametryn	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Atrazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Atrazine-desethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Atrazine-desisopropyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Azadirachtin-A	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Azinphos-ethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Azinphos-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Azoxystrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Benalaxyl, sum of isomers including Benalaxyl-M	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Benfluralin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Benomyl, Carbendazim sum expressed as Carbendazim [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Carbendazim	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017

Continued...

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CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Benthiavalicarb-isopropyl	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Bifenazate	< LQ			mg/kg	0.010		* lcms-Q 2014 Rev 0 - LC-MS/MS	07/04/2017
Bifenox	< LQ			mg/kg	0.010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Bifenthrin	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Bitertanol	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Boscalid	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Bromophos-ethyl	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Bromophos-methyl	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Bromopropylate	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Bromuconazole, sum of cis- and trans-isomers	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Bupirimate	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Buprofezin	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Butylate	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Cadusaphos	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Carbaryl	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Carbofuran (including any carbofuran generated from carbosulfan, benfuracarb or furathiocarb)	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Carbofuran-3-hydroxy	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Carbofuran and Carbofuran-3-hydroxy, sum expressed as Carbofuran [414]	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Chlordane cis	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Chlordane oxi	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Chlordane trans	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Chlordane sum of cis and trans-isomers [414]	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Chlorfenvinphos, sum of E and Z isomers	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Chlormephos	< LQ			mg/kg	0.010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	31/03/2017
Chlorotoluron	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Chlorpropham	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Chlorpyriphos ethyl	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Chlorpyriphos methyl	< LQ			mg/kg	0.010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Chlorsulfuron	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Chlorthal dimethyl	< LQ			mg/kg	0.010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Clofentezine	< LQ			mg/kg	0.010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017

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CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSIS ENDING DATE
Chlorantraniliprole (DPX E-2Y45)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Coumaphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Cyanazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Cyazofamide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Cycloate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Cycloxydim	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Cyfluthrin e Cyfluthrin beta, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Cyhalothrin lambda, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Cymoxanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Cypermethrin, including other mixtures of constituent isomers (sum of isomers)	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Cyproconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Cyprodinil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
o,p'-DDD	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
p,p'-DDD	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
o,p'-DDE	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
p,p'-DDE	< LQ			mg/kg	0,003		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
o,p'-DDT	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
p,p'-DDT	< LQ			mg/kg	0,003		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
DDT, sum, of pp'-DDT, op'-DDT, pp'-DDE, pp'DDD expressed as DDT [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Deltamethrin (cis-deltamethrin)	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Diazinon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dichlobenil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Dichlofluanid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dichlofluanid and DMSA, sum expressed as dichlofluanid [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dimethyl-sulfanilide (DMSA)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dichloran	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Dichlorvos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dietofencarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Difenoconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Diflubenzuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017

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Modena (Italy), li 07/04/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Diflufenican	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dimethenamid, sum of isomers including dimethenamid-P	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dimethoate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Omethoate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dimethoate and Omethoato, sum expressed as dimethoate [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dimethomorph, sum of isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Ditalimfos	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Diuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dodine	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Emamectin benzoate B1a, value expressed as emamectin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Endosulfan alpha	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Endosulfan beta	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Endosulfan sulphate	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Endosulphan, sum of alpha and beta isomers and of endosulfan sulphate, expressed as endosulfan [414]	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Endrin	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Epoxyconazol	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
EPTC	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Esfenvalerate and Fenvalerate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Ethion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Ethofumesate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Ethoprophos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Etofenprox	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Etoxazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Famoxadone	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenamidone	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenamiphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenamiphos-sulfoxide	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Fenamiphos-sulfone	< LQ			mg/kg	0,010		* Icms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017

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neotron

QS-feedmonitoring
QS-residuemonitoring

QS-Labor für Frisches Obst Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA

Modena (Italy), li 07/04/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE **17C17467**

Analysis beginning date **23/03/2017**

Registration date **23/03/2017**

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	CO	METHOD	ANALYSES ENDING DATE
Fenamiphos, fenamiphos-sulfone, fenamiphos-sulfoxide, sum expressed as fenamiphos [414]	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev 0 - LC-MS/MS	07/04/2017
Fenarimol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenazaquin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenbuconazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenchlorphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenchlorphos-oxon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenchlorphos and fenchlorphos-oxon sum expressed as fenchlorphos [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenhexamid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenitrothion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenoxaprop-p-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenoxycarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenpropathrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenpropidin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenpropimorph	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fenpyroximate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenthion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenthion-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenthion-oxon-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenthion-oxon-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenthion-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenthion-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fenthion, fenthion-oxon, fenthion-oxon-sulfone, fenthion-oxon-sulfoxide, fenthion-sulfone, fenthion-sulfoxide, sum expressed as fenthion [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Flazasulfuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Flucythrinate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fludioxonil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Flufenacet	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Flufenoxuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fluopicolide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Fluquinconazole	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev 1 - GC-MS/MS	31/03/2017
Flusilazole	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017

Continued...

neotron

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA

Modena (Italy), li 07/04/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Flutriafol	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Fluvalinate, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev 7 2016 - GC-MS/MS	31/03/2017
Fonofos	< LQ			mg/kg	0,010		01(S144) Rev 7 2016 - GC-MS/MS	31/03/2017
Formothion	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Fosthiazate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
HCH alpha	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
HCH beta	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
HCH delta	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
HCH epsilon	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
HCH, sum of HCH alpha, beta, delta and epsilon [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Heptachlor	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Heptachlor Epoxide cis	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Heptachlor Epoxide trans	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Heptachlor, Heptachlor Epoxide cis and Epoxide trans sum expressed as Heptachlor [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Heptenophos	< LQ			mg/kg	0,010		01(S144) Rev 7 2016 - GC-MS/MS	31/03/2017
Hexachlorobenzene	< LQ			mg/kg	0,002		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Hexaconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Hexythiazox	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Imazalil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Imidacloprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Indoxacarb, sum of R and S isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Iodofenphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Iprodione	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Iprovalicarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Isofenphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Isofenphos-methyl	< LQ			mg/kg	0,010		01(S144) Rev 7 2016 - GC-MS/MS	31/03/2017
Isoprothiolane	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Isoproturon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Kresoxim-methyl	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev 1 - GC-MS/MS	31/03/2017
Lindane	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Lindane, sum of HCH isomers included Lindane [414]	< LQ			mg/kg	0,003		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel

ACCREDIA
LAB. N°0026

Modena (Italy), li 07/04/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Linuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Lufenuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Malaoxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Malathion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Malathion and Malaoxon sum expressed as Malathion [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Mandipropamid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Mecarbam	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Mepanipyrim	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Metalaxyl, sum of isomers including Metalaxyl-M	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Metazachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Methidathion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Methiocarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Methiocarb-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Methiocarb-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Methiocarb, methiocarb sulfone and methiocarb sulfoxide, sum expressed as Methiocarb [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Methomyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Thiodicarb	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Methomyl and Thiordicarb sum expressed as Methomyl [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Methoxychlor	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Methoxyfenozide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Metolachlor, sum of isomers including S-metolachlor	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Metrafenone	< LQ			mg/kg	0,010		+ lcms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Metribuzin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Metsulfuron-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Mevinphos, sum of cis- and trans-isomers	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Molinate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Monuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln
QS-Labor für Futtermittel

ACCREDIA
LAB. N°0078

Modena (Italy), li 07/04/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Myclobutanil	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Napropamide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Oxadiazon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Oxadixyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Oxyfluorfen	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Paclobutrazol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Paraoxon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Paraoxon-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Parathion	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Parathion-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Parathion and Paraoxon sum expressed as Parathion [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Parathion-methyl and Paraoxon-methyl sum expressed as Parathion-methyl [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Penconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pencycuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pendimethalin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Permethrin, sum of isomers	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Perthane	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Phenmedipham	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phenthoate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Phorate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phorate-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phorate-sulfone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phorate-sulfoxide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phorate, phorate-oxon, phorate-sulfone and phorate-sulfoxide, sum expressed as phorate [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phosalone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phosmet	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phosmet-oxon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phosmet and phosmet-oxon expressed as phosmet [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Phosphamidon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Picoxystrobin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Piperonyl butoxide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017

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neotron SPA
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel.

ACCREDIA
LAB. N°0826

Modena (Italy), li 07/04/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Pirimicarb (Pirimor)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pirimicarb-desmethyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pirimicarb and pirimicarb-desmethyl, sum expressed as pirimicarb [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pirimiphos-ethyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Pirimiphos-methyl	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Prochloraz	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Procymidone	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Profenofos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Prometryn	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Propachlor	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Propanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Propaquizafop	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Propargite	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Propazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Propiconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Propoxur	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Propyzamide	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Proquinazid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pyraclostrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pyrazophos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pyrethrins: pyrethrin I and II, cinerin I and II, jasmolin I and II, sum (low limit)	< LQ			mg/kg	0,010		* icms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Pyridaben	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Pyrimethanil	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Pyriproxyfen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Quinalphos	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Quinoxifen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Quintozene	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Pentachloroaniline	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Quintozene and pentacloroanilin, sum expressed as quintozene [414]	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017

Continued...

neotron S.p.A.
ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln.
QS-Labor für Futtermittel.

ACCREDIA
LAB. N°0026

Modena (Italy), li 07/04/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Rotenone	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Simazine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Spinosad, sum of spinosyn A and spinosyn D	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Spirodiclofen	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Spirotetramat	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Spirotetramat enol	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Spirotetramat enol-glucoside	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Spirotetramat ketohydroxy	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Spirotetramat monohydroxy	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Spirotetramat and its metabilites (enol, enol-glucoside, ketohydroxy, monohydroxy) sum as spirotetramat [414]	< LQ			mg/kg	0,010		* lcms-Q 2014 Rev.0 - LC-MS/MS	07/04/2017
Spiroxamine	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Sulfallate	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Sulfotep	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Tebuconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Tebufenozide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Tebufenpyrad	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Teflubenzuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Tefluthrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Terbuthylazine	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Tetrachlorvinphos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Tetraconazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Tetradifon	< LQ			mg/kg	0,010		01(P8) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Tetramethrin	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Thiabendazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Thiacloprid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Thiamethoxam	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Thiobencarbe	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Thionazin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017

Continued...

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ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
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QS-Labor für Frisches Obst Gemüse und Kartoffeln
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ACCREDIA
LAB. N°0076

Modena (Italy), li 07/04/2017 Page 11 di 12

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Thiophanate-methyl	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Tolclofos-methyl	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Tolylfluanid	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Dimethylaminosulphotoluidide (DMST)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Tolylfluanid and DMST, sum expressed as tolylfluanid [414]	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Triadimefon	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Triadimenol	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Triadimefon and Triadimenol, sum [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Triallate	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Di-allate (sum of isomers)	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Triallate and Diallate sum expressed as Triallate [414]	< LQ			mg/kg	0,010		01(S144) Rev.7 2016 - GC-MS/MS	31/03/2017
Triazophos	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Trichlorfon	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Tricyclazole	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Trifloxystrobin	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Triflumuron	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Trifluralin	< LQ			mg/kg	0,010		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017
Triticonazole	< LQ			mg/kg	0,010		* GCMS-Q 2016 Rev.1 - GC-MS/MS	31/03/2017
Vamidothion	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017
Vinchlozolin	< LQ			mg/kg	0,005		01(P6) rev11 2007 + (P/R/C-G2) rev5 2015 - GC-ECD	03/04/2017

Continued...

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ANALYTICAL AND TECHNICAL SERVICES

QS-feedmonitoring
QS-residuemonitoring
QS-Labor für Frisches Obst, Gemüse und Kartoffeln
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ACCREDIA
LAB. N°0026

Modena (Italy), li 07/04/2017

CUSTOMER
BASF Personal Care and Nutrition GmbH
Robert Hansen Strasse 1
89257 Illertissen GERMANIA

TEST REPORT nr. 17C17467-In-0

SAMPLE 17C17467

Analysis beginning date 23/03/2017

Registration date 23/03/2017

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Zoxamide	< LQ			mg/kg	0,010		01(S121) rev5 2017 - LC-MS/MS	07/04/2017

END TEST REPORT

Notes and method reference:
< LQ: = lower than Quantification Limit. Please note that results expressed as '<LQ' may not indicate the absence of the searched parameters in the sample.
U: the reported uncertainty is the expanded uncertainty calculated using a coverage factor equal to 2 which gives a reliability of approximately 95%. For microbiological detections it is reported either the lower and the upper bounds of the confidence interval with a probability of 95% K=2 or the confidence interval itself.
Results coming from microbiological tests are calculated according to the Standard ISO 7218:2007/Amd 1:2013. If the results are reported as <4 (CFU/ml) or <40 (CFU/g), this means that the microorganisms are present in the sample but in amounts less than 4 CFU/ml or 40 CFU/g respectively.
LQ: Quantification Limit. It is the lowest analyte concentration which can be detected at an acceptable precision (repeatability) and accuracy, under well defined conditions.
LD: Detection Limit. It is the lowest analyte concentration which can be detected but not necessarily quantified, under well defined conditions.
Conformity evaluation: values not complying with laws, decrees, national and EU regulations or specifications supplied by the customer are evaluated case by case, also taking into consideration the uncertainty of measure for each single test and the regulations on rounding-off of values, and pointed out when considered as "non conform".
Rec %: Recovery % "+" means that the recovery has been applied to the result. The numeric results between brackets (..) after the espression <LQ are purely indicative of traces that cannot be exactly quantified.
Methods marked with an asterisk (*) are not accredited by ACCREDIA (UNI CEI EN ISO/IEC 17025)

NOTES OF PARAMETERS:
[414]: The sum is calculated through the lower bound criterion.

TEST REPORT VALID FOR ALL LEGAL PURPOSES (Italian R.D. 1-3-1928 n°842 (article 16), – Italian Law 19-7-1957 n°679 articles 16 and 18, Italian Ministerial Decree 25-3-1986).
Test Report issued according to the 17025:2005 Standard
DATA and SAMPLE STORAGE: Raw data, chromatographic paths and instrumental reports are stored for 5 years. One control sample is stored for 2 months.
Data expressed in this test report refer only to the sample tested in the laboratory. The description or any other reference concerning the sample are declared by the customer. This Test Report cannot be reproduced except in full. Partial reproductions must be authorized in writing by our laboratory.

LABORATORY MANAGER: DR. GIAN CARLO GATTI - MEMBER OF AOAC N. VM 90231001 - EURCHEM
Approved by Analysis Manager - laboratory LMIA-pest

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GMP Pharmaceutical Laboratories Authorized by AIFA Italian Medicine Agency n° aM- 55/2015.
Laboratorio Qualificato D.M. 26-2-87 Art. 4 - Legge 46/82 per la Ricerca Applicata e Innovazione Tecnologica.
Regione Emilia Romagna - AUTORIZZAZIONE Autocontrollo N° 008/MO/008
BNN-Monitoring Fruit and Vegetables Approved Laboratory
I-Monitoring EDEKA AG Fruit and Vegetables Registered Laboratory

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Body of Certificate

Please note that the certificates of analysis are also conveniently available online and around the clock at www.worldaccount.basf.com

2017-08-23
QC
Dorthe Loeb
+45 447 30-255
Reg. 20170821140928

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

0,5KG PE-Bag

Material 50391929

Lot 0017388007

Characteristic	Unit	Value	Lower Limit	Upper Limit	Method
DHA (calculated as Triglycerides)	%	11.6	10.5		GC
DHA (calculated as Fatty Acids)	%	11.2	10.0		Calculated value
Appearance*		- OK			Visual
Through mesh 20 USP	%	100	100		Sieving
Through mesh 40 USP	%	97	90		Sieving
Through mesh 120 USP	%	0		12	Sieving
Loss on drying	%	4		5	Gravimetric
Anisidin value		3		15	Spectrophotometric
Peroxide value	mEq/KG	0		2	Titrimetric
Free fat	%	0.1			Gravimetric
Total aerobic microbial count (TAMC)	1/g	< 100		1000	Ph.Eur./USP
Salmonella		- Absence			ISO 6579 30x25g P
Total yeast and moulds count (TYMC)	1/g	< 20		30	Ph.Eur./USP
Staphylococcus aureus		- Absence in 10g			USP
Cronobacter spp.		- "Absence in 300g"			ISO/TS 22964

Additional Information

Production Date: 26.06.2017

Date of analysis: 11.07.2017

Best before / Retest date: 26.06.2019

Inspection lot no: 300017735227

Appearance*: Light yellow to light beige free-flowing dry powder

2017-08-23
QC
Dorthe Loeb
+45 447 30-255

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

0,5KG PE-Bag

Material 50391929

Lot 0017388007

consisting of spherical particles.

Confirmation, based on random sampling:

Lead	max. 0.02 mg/kg	
Cadmium	max. 0.01 mg/kg	
Mercury	max. 0.02 mg/kg	
Arsenic	max. 0.1 mg/kg	
Sulph. red. clostridia	<(><<)>10 CFU/g	NMKL 56
Clostridium Perfringens	<(><<)>10 CFU/g	ISO 7937
E. coli	Abs. in 10 g	Ph.Eur./USP
Ps. Aeruginosa	Abs. in 10 g	Ph.Eur./USP
Bac. cereus	<(><<)>100 CFU/g	ISO 7932
Enterobacteria	Abs. in 1g	ISO 21528

Manufacturer:
BASF A/S
Malmparken 5
DK-2750 Ballerup
Denmark
BASF A/S
Quality Assurance
Malmparken 5
2750 Ballerup
Denmark

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2017-08-23
QC
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Reg. 20170821105040

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

0,5KG PE-Bag

Material 50391929

Lot 0017387993

Characteristic	Unit	Value	Lower Limit	Upper Limit	Method
DHA (calculated as Triglycerides)	%	11.8	10.5		GC
DHA (calculated as Fatty Acids)	%	11.4	10.0		Calculated value
Appearance*		OK			Visual
Through mesh 20 USP	%	100	100		Sieving
Through mesh 40 USP	%	97	90		Sieving
Through mesh 120 USP	%	0		12	Sieving
Loss on drying	%	4		5	Gravimetric
Anisidin value		2		15	Spectrophotometric
Peroxide value	mEq/KG	0		2	Titrimetric
Free fat	%	0.1			Gravimetric
Total aerobic microbial count (TAMC)	1/g	< 100		1000	Ph.Eur./USP
Salmonella		Absence			ISO 6579 30x25g P
Total yeast and moulds count (TYMC)	1/g	< 20		30	Ph.Eur./USP
Staphylococcus aureus		Absence in 10g			USP
Cronobacter spp.		"Absence in 300g"			ISO/TS 22964

Additional Information

Production Date: 26.06.2017

Date of analysis: 11.07.2017

Best before / Retest date: 26.06.2019

Inspection lot no: 300017735224

Appearance*: Light yellow to light beige free-flowing dry powder

Please note that the certificates of analysis are also conveniently available online and around the clock at www.worldaccount.basf.com

2017-08-23
QC
Dorthe Loeb
+45 447 30-255
Reg. 20170821105040

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

0,5KG PE-Bag

Material 50391929

Lot 0017387993

consisting of spherical particles.

Confirmation, based on random sampling:
Lead max. 0.02 mg/kg
Cadmium max. 0.01 mg/kg
Mercury max. 0.02 mg/kg
Arsenic max. 0.1 mg/kg

Sulph. red. clostridia <(><<)>10 CFU/g NMKL 56
Clostridium Perfringens <(><<)>10 CFU/g ISO 7937
E. coli Abs. in 10 g Ph.Eur./USP
Ps. Aeruginosa Abs. in 10 g Ph.Eur./USP
Bac. cereus <(><<)>100 CFU/g ISO 7932
Enterobacteria Abs. in 1g ISO 21528

Manufacturer:
BASF A/S
Malmparken 5
DK-2750 Ballerup
Denmark
BASF A/S
Quality Assurance
Malmparken 5
2750 Ballerup
Denmark

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2017-08-23
QC
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Reg. 20170821140352

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

0,5KG PE-Bag

Material 50391929

Lot 0017387977

Characteristic	Unit	Value	Lower Limit	Upper Limit	Method
DHA (calculated as Triglycerides)	%	12.1	10.5		GC
DHA (calculated as Fatty Acids)	%	11.7	10.0		Calculated value
Appearance*		- OK			Visual
Through mesh 20 USP	%	100	100		Sieving
Through mesh 40 USP	%	97	90		Sieving
Through mesh 120 USP	%	0		12	Sieving
Loss on drying	%	3		5	Gravimetric
Anisidin value		2		15	Spectrophotometric
Peroxide value	mEq/KG	0		2	Titrimetric
Free fat	%	0.1			Gravimetric
Total aerobic microbial count (TAMC)	1/g	< 100		1000	Ph.Eur./USP
Salmonella		- Absence			ISO 6579 30x25g P
Total yeast and moulds count (TYMC)	1/g	< 20		30	Ph.Eur./USP
Staphylococcus aureus		- Absence in 10g			USP
Cronobacter spp.		- "Absence in 300g"			ISO/TS 22964

Additional Information

Production Date: 25.06.2017

Date of analysis: 06.07.2017

Best before / Retest date: 25.06.2019

Inspection lot no: 300017735219

Appearance*: Light yellow to light beige free-flowing dry powder

2017-08-23
QC
Dorthe Loeb
+45 447 30-255
Reg. 20170821140352

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

0,5KG PE-Bag

Material 50391929

Lot 0017387977

consisting of spherical particles.

Confirmation, based on random sampling:
Lead max. 0.02 mg/kg
Cadmium max. 0.01 mg/kg
Mercury max. 0.02 mg/kg
Arsenic max. 0.1 mg/kg

Sulph. red. clostridia <(><<)>10 CFU/g NMKL 56
Clostridium Perfringens <(><<)>10 CFU/g ISO 7937
E. coli Abs. in 10 g Ph.Eur./USP
Ps. Aeruginosa Abs. in 10 g Ph.Eur./USP
Bac. cereus <(><<)>100 CFU/g ISO 7932
Enterobacteria Abs. in 1g ISO 21528

Manufacturer:
BASF A/S
Malmparken 5
DK-2750 Ballerup
Denmark
BASF A/S
Quality Assurance
Malmparken 5
2750 Ballerup
Denmark

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2017-08-18
QC
DORTHE LOEB
+45 447 30-255
Reg. 20160629115333

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

Material 50391929

0,5KG PE-Bag

Lot 0011806723

Characteristic	Unit	Value	Lower Limit	Upper Limit	Method
DHA (calculated as Triglycerides)	%	13.1	10.5		GC
DHA (calculated as Fatty Acids)	%	12.6	10.0		Calculated value
Appearance*		OK			Visual
Through mesh 20 USP	%	100	100		Sieving
Through mesh 40 USP	%	99	90		Sieving
Through mesh 120 USP	%	0		12	Sieving
Loss on drying	%	3		5	Gravimetric
Anisidin value		4		15	Spectrophotometric
Peroxide value	mEq/KG	0		2	Titrimetric
Free fat	%	0.1			Gravimetric
Total aerobic microbial count (TAMC)	1/g	< 100		1000	Ph.Eur./USP
MPN coliforms	1/g	< 0.3			Microbiological
Salmonella		Absence			ISO 6579 30x25g P
Yeast and Mould					Ph.Eur./USP
Staphylococcus aureus		Absence in 10g			USP
Cronobacter spp.		"Absence in 300g"			ISO/TS 22964

Additional Information

Production Date: 25.04.2014

Date of analysis: 14.05.2014

Best before / Retest date: 21.01.2017

Inspection lot no: 300013908665

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2017-08-18
QC
DORTHE LOEB
+45 447 30-255
Reg. 20160629115333

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

0,5KG PE-Bag

Material 50391929

Lot 0011806723

Quality Assurance
Malmparken 5
2750 Ballerup
Denmark

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2017-08-23
QC
Dorthe Loeb
+45 447 30-255
Reg. 20170822082453

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

0,5KG PE-Bag

Material 50391929

Lot 0017387946

Characteristic	Unit	Value	Lower Limit	Upper Limit	Method
DHA (calculated as Triglycerides)	%	11.7	10.5		GC
DHA (calculated as Fatty Acids)	%	11.3	10.0		Calculated value
Appearance*		- OK			Visual
Through mesh 20 USP	%	100	100		Sieving
Through mesh 40 USP	%	97	90		Sieving
Through mesh 120 USP	%	0		12	Sieving
Loss on drying	%	3		5	Gravimetric
Anisidin value		2		15	Spectrophotometric
Peroxide value	mEq/KG	0		2	Titrimetric
Free fat	%	0.1			Gravimetric
Total aerobic microbial count (TAMC)	1/g	< 100		1000	Ph.Eur./USP
Salmonella		- Absence			ISO 6579 30x25g P
Total yeast and moulds count (TYMC)	1/g	< 20		30	Ph.Eur./USP
Staphylococcus aureus		- Absence in 10g			USP
Cronobacter spp.		- "Absence in 300g"			ISO/TS 22964

Additional Information

Production Date: 25.06.2017

Date of analysis: 18.08.2017

Best before / Retest date: 25.06.2019

Inspection lot no: 300017735215

Appearance*: Light yellow to light beige free-flowing dry powder

2017-08-23
QC
Dorthe Loeb
+45 447 30-255
Reg. 20170822082453

Certificate of Analysis according to DIN 55350-18-4.2.2

Dry n-3® DHA 11A

Material 50391929

0,5KG PE-Bag

Lot 0017387946

consisting of spherical particles.

Confirmation, based on random sampling:
Lead max. 0.02 mg/kg
Cadmium max. 0.01 mg/kg
Mercury max. 0.02 mg/kg
Arsenic max. 0.1 mg/kg

Sulph. red. clostridia <(><<)>10 CFU/g NMKL 56
Clostridium Perfringens <(><<)>10 CFU/g ISO 7937
E. coli Abs. in 10 g Ph.Eur./USP
Ps. Aeruginosa Abs. in 10 g Ph.Eur./USP
Bac. cereus <(><<)>100 CFU/g ISO 7932
Enterobacteria Abs. in ig ISO 21528

Manufacturer:
BASF A/S
Malmparken 5
DK-2750 Ballerup
Denmark
BASF A/S
Quality Assurance
Malmparken 5
2750 Ballerup
Denmark

APPENDIX B

Stability Testing

TABLE OF CONTENTS

Newtrition

Stability data - Ongoing

Version 3, 12.2018

DHA Algal Oil

PRD no. 30599327
Manufacturing site: BASF Personal Care and Nutrition GmbH, Illertissen, Germany

Storage conditions and stability study information:
Stability tests for DHA Algal Oil produced in commercial scale have been started in March 2017. The first time point for results are expected by end of September 2017. The storage test is carried out at the following defined climatic conditions:
≤ -18°C
+2 to +8°C

The ongoing stability test is presented below. This data provides the justification for the stated shelf life of DHA Algal Oil.

Analytical method:
Please refer to the table below.

Packaging:
The stability test is conducted on product packaged in a 25kg metal drum, same as the primary packaging material used for storage and distribution of the 25kg sales product. This packaging is also of an equivalent quality compared to the 190kg metal drum sales article.

Test attributes:
The stability study includes testing of those attributes that are susceptible to change during storage and is likely to influence the quality, safety and/or efficacy.

Long term stability study (ongoing):
DHA Algal Oil at ≤ -18°C (m: months); Lot 0016888247; Test start: 13.03.2017

Parameter	Specification	Unit	Method	Start	6 m	12 m	18 m	24 m
Appearance	Clear to turbid, yellow to orange liquid		AX-001001	conforms	conforms	conforms	conforms	
Acid value	≤ 0.5	mgKOH/g	ISO 660	0.1	0.1	0.1	0.1	
Peroxide value	≤ 4.0	meq O/kg	CP-001009	0.1	0.4	0.5	0.4	
Anisidine value	≤ 15	-	ISO 6885	2.5	2.8	2.7	2.7	
DHA as TG	≥ 380	mg/g	PhEur 2.4.29	403	413	401	409	
Total tocopherols	No limit	mg/kg	IA-005034	2993	3011	3088	3036	
Total aerobic plate count	Max. 1000	cfu/g	MB-002035	<10	-	-	-	
Yeast and mould	Max. 100	cfu/g	MB-002039	<10	-	-	-	
Enterobacteria	Neg/10g		MB-008052	negative	-	-	-	
Salmonella	Neg/25g		MB-001053	negative	-	-	-	

Long term stability study (ongoing):
DHA Algal Oil at +2 to +8°C (m: months); Lot 0016888247; Test start: 13.03.2017
*outlier result, sample drawn from top of drum slightly up-concentrated in DHA and tocopherols

Parameter	Specification	Unit	Method	Start	6 m	12 m	18 m
Appearance	Clear to turbid, yellow to orange liquid		AX-001001	conforms	conforms	conforms	Conforms
Acid value	≤ 0.5	mgKOH/g	ISO 660	0.1	0.1	0.1	0.1
Peroxide value	≤ 4.0	meq O/kg	CP-001009	0.1	0.9	0.5	2.8
Anisidine value	≤ 15	-	ISO 6885	2.5	2.6	2.0	3.0
DHA as TG	≥ 380	mg/g	PhEur 2.4.29	403	417	436*	425
Total tocopherols	No limit	mg/kg	IA-005034	2993	3051	3453*	3209
Total aerobic plate count	Max. 1000	cfu/g	MB-002035	<10	-	-	-
Yeast and mould	Max. 100	cfu/g	MB-002039	<10	-	-	-
Enterobacteria	Neg/10g		MB-008052	negative	-	-	-
Salmonella	Neg/25g		MB-001053	negative	-	-	-

Conclusion:

Ongoing stability test has shown that this product is stable for at least 24 months,
when it is stored in the original unopened container at frozen conditions of ≤ -18°C, respectively +2 to +8°C.

The above listed data demonstrates that DHA Algal Oil is justified for the following stability in the original unopened container:

- At refrigerated conditions of +2 to +8°C the product is stable for min. 12 months.
- At frozen conditions at ≤ -18°C the product will keep for min. 24 months.

Newtrition

Stability data

Version 1, 07.2017

Dry n-3® DHA 11A

PRD no. 30602682
Manufacturing site: BASF A/S, Ballerup, Denmark

Stability study (no.): FS-000108 (1 batch)

Storage conditions:
Defined climatic conditions: 25°C ± 2°C/ 60% RH ± 5% RH
30°C ± 2°C/ 65% RH ± 5% RH
40°C ± 2°C/ 75% RH ± 5% RH

Analytical method: DHA assay: gas chromatography
Ansidine value: spectrophotometric
Peroxid value: titrimetric

Packaging:
The stability test is conducted on product packaged in water-resistant aluminum-foil bags, similar to the primary packaging material used for storage and distribution of sales product.

Test attributes:
The stability study includes testing of those attributes that are susceptible to change during storage and is likely to influence the quality, safety and/or efficacy.
Assay and oxidation, as the most important measure for the product quality and efficacy, are summarized below.

Long term stability study:
Dry n-3 DHA 11A stored at 25°C ± 2°C/ 60% RH ± 5% RH

DHA in % as triglycerides (m: months, n.d not determined)

Batch	Start of the study	Specification	0 m	3 m	6 m	9 m	12 m	18 m	24 m	36 m
0011806723	14.05.2014	Min.10.5	13.1	n.d.	n.d	n.d	12.2	n.d	12.9	12.6

DJ 17.07.2017
NSB 17 JULI 2017

Anisidine value (m: months)

Batch	Start of the study	Specification	0 m	3 m	6 m	9 m	12 m	18 m	24 m	36 m
0011806723	14.05.2014	Max 15	3.8	2.1	3.7	3.1	1.4	2.7	2.9	2.4

Peroxide value meq/kg (m: months)

Batch	Start of the study	Specification	0 m	3 m	6 m	9 m	12 m	18 m	24 m	36 m
0011806723	14.05.2014	Max. 2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Intermediate stability study:
Dry n-3 DHA 11A stored at 30°C +/-2°C/ 65% RH +/- 5% RH
Assay: DHA in % as triglycerides (m: months, n.d not determined)

Batch	Start of the study	Specification	0 m	3 m	6 m	9 m	12 m	18 m	24 m	36 m
0011806723	14.05.2014	Min.10.5	13.1	n.d.	n.d.	n.d.	12.2	n.d	12.8	12.5

Anisidine value (m: months)

Batch	Start of the study	Specification	0 m	3 m	6 m	9 m	12 m	18 m	24 m	36 m
0011806723	14.05.2014	Max.15	3.8	1.8	2.8	3.0	3.0	2.7	1.3	2.2

Peroxide value meq/kg (m: months)

Batch	Start of the study	Specification	0 m	3 m	6 m	9 m	12 m	18 m	24 m	36 m
0011806723	14.05.2014	Max. 2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Accelerated stability study:
Dry n-3 DHA 11A stored at 40°C ± 2°C/ 75% RH ± 5% RH
DHA in % as triglycerides (m: months, n.d not determined)

Batch	Start of the study	Specification	0 m	3 m	6 m
0011806723	01.09.2009	Min. 10.5	13.1	n.d.	12.7

Anisidine value (m: months, n.d not determined)

Batch	Start of the study	Specification	0 m	3 m	6 m
0011806723	14.05.2014	Max.15	3.8	3.9	2.6

Peroxide value meq/kg (m: months, n.d not determined)

Batch	Start of the study	Specification	0 m	3 m	6 m
0011806723	14.05.2014	Max. 2	0.0	0.0	0.0

Conclusion (based on the data listed above):

Dry n-3 DHA 11A is stable for at least 24 months, when it is stored in the original unopened container at max. 25°C. Data is taken from a study containing one batch only, as no more than one batch has been produced and included so far.

From:	Don Schmitt
To:	Downey, Jason
Cc:	Haresh P Madeka; Juergen Gierke; Bernd Haber; Herbert Roth
Subject:	Re: GRN 862 - DHA Algal Oil - Follow Up Questions
Date:	Friday, September 27, 2019 6:03:23 PM
Attachments:	image002.png BASF GRN 862 Responses 092719.pdf

Dear Dr. Downey,

We have attached responses to all of the follow up questions raised by FDA in your email dated September 19, 2019. Please let me know if you have any further needs.

Best regards,

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540
phone: 630.352.0303
email: dschmitt@toxstrategies.com

From: "Downey, Jason" <Jason.Downey@fda.hhs.gov>
Date: Thursday, September 19, 2019 at 2:31 PM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 862 - DHA Algal Oil - Follow Up Questions

Dear Mr. Schmitt,

1. You have provided specifications for the *Schizochytrium* sp. T-18 algal oil (Table 3, p. 15) and the *Schizochytrium* sp. T-18 algal oil powder (Table 4, p. 16). These specifications, particularly for the oil form of the ingredient (Table 3), appear incomplete and are different from the specifications for "DHA from algal *Schizochytrium* oil," stated in the Food Chemicals Codex 11 (FCC, 2019) monograph for this ingredient. The FCC specifications are commonly cited as standards for food-grade ingredients. While it is possible that your ingredient might not meet all of the FCC specifications for levels of certain fatty acids, we request that you provide a comparison of the specifications for the *Schizochytrium* sp. T-18 algal oil to the FCC specifications for "DHA from algal *Schizochytrium* oil," and if differences are observed, please address why these are not relevant to your safety determination. If specifications are not included in your notice but are included in the FCC monograph, we ask that you include these specifications for the T-18 algal oil in an amendment to your notice. Please provide the results of at least three non-consecutive batch analyses confirming the T-18 algal oil meets these specifications. In your comparison of *Schizochytrium* sp. T-18 algal oil to the FCC specifications, we ask that you address the following:

Parameter	**DHA Algal Oil**	**FCC Specifications (2019)**
Appearance	Clear to turbid, yellow to orange liquid	NA
Acid value (mg KOH/g)	≤ 0.5	NA
Free fatty acids (% as oleic acid)	≤ 0.25	≤ 0.4
Peroxide value (meq O^2/kg)	≤ 4.0	≤ 5.0
Total oxidation value	≤ 23.0	≤26.0
Anisidine value	≤ 15	≤20.0
Unsaponifiable matter (weight %)	≤ 3.5	≤4.5
Moisture (weight %)	≤ 0.05	NA
DHA (mg/g as triglyceride)*	≥ 380	30-40 (area %) or 300-400
Trans fatty acids (area-%)	≤ 1.0	NA
Iron (Fe) (mg/kg)	≤ 0.2	NA
Copper (Cu) (mg/kg)	≤ 0.05	NA

*It is possible in the future that a DHA algal oil and powder of lower potency, such as 35% DHA in algal oil and 11% in powder, could be manufactured and used accordingly by infant formula manufacturers.

a. Specified limits/ranges for fatty acid composition (dihomo gamma linolenic acid (DGLA), arachidonic acid (ARA), eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA), docosahexaenoic acid (DHA))

Response: As indicated in Table 6 of GRM 862 and the abbreviated table below, DGLA values for four batches of the proposed DHA algal oil are 0.1 (area %); ARA values range from 0.2-0.3 (area %); EPA values range from 1.5-1.7 (area %); DPA values range from 7.2-

8.1 (area %); and DHA values range from 41.1-44.5% (area %). It is the opinion of BASF that the slight variation in fatty acid content compared to the FCC specifications has no appreciable effect on the quality or safety of the proposed DHA algal oil for use in food and infant formula. The following table is a side-by-side comparison of four non-consecutive lots of BASF DHA algal oil and FCC specifications.

Fatty Acids		**DHA Algal Oil [Area %]**				
		DH5750	**DH5751**	**DH5752**	**0016888247**	**FCC specs**
20:3 (n-6)	Dihomo gammalinolenic acid	0.1	0.1	0.1	0.1	1.7 - 2.8
20:4 (n-6)	Arachidonic acid	0.3	0.3	0.2	0.3	0.6 - 1.3
20:5 (n-3)	Eicosapentaenoic acid EPA	1.6	1.7	1.5	1.7	1.3 - 1.9
22:5 (n-6)	Docosapentaenoic acid DPA	8.1	7.8	7.2	7.7	10.5 - 16.5
22:6 (n-3)	Docosahexaenoic acid DHA	44.5	44.2	41.1	41.7	30.0 - 40.0

b. Limits for heavy metals (As, Pb, Hg)

Response: As indicated in Table 8 of GRM 862 and the abbreviated table below, the levels of arsenic, lead, and mercury are below FCC specifications and the limits set in the FCC specifications for heavy metals are acceptable for BASF's DHA algal oil. The following table is a side-by-side comparison of four non-consecutive lots of BASF DHA algal oil and FCC specifications.

Elemental Analysis						
	DH5750	**DH5751**	**DH5752**	**016888247**	**BASF Internal Limits**	**FCC Specs**
Arsenic (ppm)	<0.1	<0.1	<0.1	<0.1	≤0.1	≤0.1
Lead (ppm)	<0.02	<0.02	<0.02	<0.05	≤0.1	≤0.1
Mercury (ppm)	<0.005	<0.005	<0.005	<0.005	≤0.01	≤0.1

c. Limit for percent free fatty acids

Response: The free fatty acids are controlled via the acid value parameter. The limit for free fatty acids is ≤0.25% calculated as oleic acid.

d. Analytical methods used to verify compliance with specifications. If internal methods were used please state if they were validated.

Response: All test methods employed are referenced in Appendix A of GRN 862 along with the batch analytical data. The methods are also included in the following table. All methods are validated.

Parameter	FCC Specifications (2019)	Analytical Methods Used
Acid value (mg KOH/g)	NA	ISO 660
Free fatty acids (% as oleic acid)	≤ 0.4	ISO 660
Peroxide value (meq O^2/kg)	≤ 5.0	ISO 3960
Total oxidation value	≤26.0	Per FCC
Anisidine value	≤20.0	DIN EN ISO 6885
Unsaponifiable matter (weight %)	≤4.5	PhEur 2.5.7
DHA (area %)	30 - 40	PhEur 2.4.29
Dihomo gammalinolenic acid (DGLA)	1.7 – 2.8	PhEur 2.4.29 (GC-FID)
Arachidonic acid	0.6 -1.3	PhEur 2.4.29 (GC-FID)
Eicosapentaenoic acid EPA)	1.3 – 3.9	PhEur 2.4.29 (GC-FID)
Docosapentaenoic acid (DPA)	10.5 – 16.5	PhEur 2.4.29 (GC-FID)
Arsenic (mg/kg)	≤0.1	EN 15763:2009, CON-PV 01274, ICP-MS
Lead (mg/kg)	≤0.1	EN 15763:2009, CON-PV 01274, ICP-MS
Mercury (mg/kg)	≤0.1	EN 15763:2009, CON-PV 01274, ICP-MS

2. On page 15 (Table 3), you did not state specifications for microbiological contaminants for the T-18 algal oil although you state an intended use is in infant formula. We note that such specifications are provided for the T-18 algal oil powder and that Appendix A includes results from batch analyses testing for microbial contaminants in the T-18 algal oil. Specified limits for microbiological contaminants help ensure that infant formula products that contain the T-18 algal oil are in compliance with 21 CFR 106.55. Please provide or discuss limits for microorganisms in the T-18 algal oil.

Response: BASF DHA algal oil is monitored for microbiological contaminants to meet the following limits:

Total aerobic mesophilic plate count: max.; 1000 cfu/g
Yeasts and molds; max. 100 cfu/g
Enterobacteria; negative/1g
Salmonella; negative/25g
Staphylococcus coagulase pos.; negative/1g
Pseudomonas aeruginosa; negative/1g

Products are tested by in-house validated methods. Analytical reports of the presented batches by accredited third party lab confirms these limits.

3. You describe the method of manufacture of *Schizochytrium* sp. T-18 algal oil which appears different from that described in GRN 677. We note that the method of purification influences the impurities in the final product. Please compare the method of manufacture and resulting impurities to that described in GRN 677 for algal oil produced from the same strain (T-18) of *Schizochytrium,* since the safety studies cited in GRN 862 were conducted using *Schizochytrium* sp. T-18 algal oil refined in accordance with the methods described in GRN 677. We ask that you address the following:

a. Clarify if the enzyme used to disrupt the cells is the same as that in GRN 677 and GRN 553 (alcalase, 21 CFR 184.1150).

Response: Yes, it is the same enzyme (alcalase) cited in GRN 677 as the starting crude DHA algal oil used by BASF is produced by MARA, the submitter of GRN 677.

b. Clarify if the degumming step is intentionally omitted in your method of manufacture. If yes, please provide a brief statement of why the degumming step is not needed.

Response: Yes, degumming is intentionally omitted. Crude algal oil derived from the disrupted cell walls through aqueous processing contains no significant amounts of phospholipids as well as low amounts of free fatty acids. This material can be directly processed without necessary degumming. This is different in comparison to solvent extracted oils.

c. Clarify if the winterization step is intentionally omitted in your method of manufacture. If it is an optional step, please clarify when it would be used and how it would influence the resultant fatty acid profile.

Response: Yes, winterization is intentionally omitted. The saturated fatty acid which will be the main cause of crystallization is palmitic acid (approx. 20%). This fatty acid is the main fatty acid in mother's milk and infant formula products. Thus, the fatty acid is intentionally kept in the oil. All algal oils provided for infant nutrition are also not winterized ingredients. Winterization would slightly lower the amount of saturated fatty acids such as palmitic acid by a few percent and vice versa increase the polyunsaturated content by a few percent. No major changes will be seen, as fatty acids are present as triacylglycerols in which saturated and unsaturated fatty acids are bound into one triglyceride molecule.

d. Indicate whether a refining step is included in your method of manufacture. If not, please clarify:

i. if the deodorization step is relied on to remove free fatty acids, and

Response: Yes, the oil is refined through a bleaching and deodorization process analogous to conventional oil refining. The bleaching process reduces the color, oxidation, and ensures low levels of environmental contaminants (such as heavy metals, polyaromatic hydrocarbons, etc.). Deodorization is mainly for optimizing sensory

attributes, but also purifies the oil in terms of free fatty acids, potential oxidation by-products, and other volatile substances. As indicated above, the aqueous processed crude oil contains only minor amounts of free fatty acids, therefore this refining process is adequate to ensure product specifications are met.

ii. if this is a change from the method of manufacture described in GRN 677. We note that the method described in GRN 677 does not explicitly describe a refining procedure, although it includes a "refined oil" step on the flow chart (Fig. 3, p. 12 of GRN 677).

Response: GRN 677 describes a general refining process as applied for vegetable oils. This is analogous to the BASF process that applies general refining (bleaching and deodorization).

e. Please provide a comparison of the composition of your *Schizochytrium* sp. T-18 algal oil with that of the GRN 677 *Schizochytrium* sp. T-18 algal oil that was the subject of safety studies cited in your GRN.

Response: The specifications for BASF DHA Algal oil are the same or more stringent when compared to MARA's DHA algal oil that was the subject of GRN 677.

Parameter	**DHA Algal Oil**	**MARA GRN 677**
Acid value (mg KOH/g)	≤ 0.5	≤ 0.5
Peroxide value (meq O^2/kg)	≤ 4.0	≤ 5.0
Moisture (%)	≤ 0.05	≤ 0.05
Anisidine value	≤ 15	NA
Unsaponifiable matter (weight %)	≤ 3.5	≤3.5
DHA (mg/g as triglyceride)*	≥ 380	≥ 350
Trans fatty acids (area-%)	≤ 1.0	≤ 2.0
Iron (Fe) (mg/kg)	≤ 0.2	<0.2
Copper (Cu) (mg/kg)	≤ 0.05	<0.1
Mercury (mg/kg)	≤ 0.02	<0.1
Lead (mg/kg)	≤ 0.02	<0.1
Arsenic (mg/kg)	≤ 0.1	<0.1

f. You note an optional distillation step.

i. Please clarify the criteria used to determine if distillation is necessary. For example, what levels of free fatty acids and sterols would trigger the distillation step?

Response: BASF algal oil is specified with an acid value of max. 0.5mg KOH/g (equal to 0.25% free fatty acids) and with a content of unsaponifiable matter of max. 3.5% (unsaponifiable matter, mainly consisting of sterols). Finished products that do not meet these criteria would trigger the need for additional distillation. Respectively, raw materials exceeding the unsaponifiable matter limit of 3.5%, or having acid values of higher than 1 mg KOH/g , or free fatty acids greater than 0.5% would also trigger the need for distillation.

ii. Please describe how use of the distillation step influences the final levels of free fatty acids and sterols in the algal oil.

Response: Free fatty acids as well as free sterols have a lower molecular weight and a lower boiling point compared to triacylglycerols (triglycerides). Thus, they can be reduced by molecular distillation (physical raffination). However, sterols cannot be reduced to zero levels. Some sterols which are bound as sterol esters have higher boiling points and therefore a certain small percentage of sterols will remain in the product.

4. You present analytical results for four lots of the *Schizochytrium* sp. T-18 algal oil (Table 5, p. 17). The value for unsaponifiable matter for lot DH571 (0.09 wt%) does not correlate with the data provided in Appendix A on p. 81. Please correct this value in Table 5 for the record.

Response: The value for unsaponifiable matter should read 0.9 wt%, not 0.09 wt%.

5. In Appendix A, you provide results of batch analyses for a number of contaminants.

a. It is not clear why pesticides would be expected to be present in a product derived from controlled fermentation. Please clarify why you analyzed for pesticides and how these data support your safety conclusions.

Response: BASF routinely conducts analyses for many contaminants as the requirements in other countries/regions may require their analysis. We agree that pesticides would not be expected to be present in the DHA algal oil and the analyses for their presence was only conducted for completion of BASF's standard of analysis for oils (e.g., plant sourced oils).

b. You provide results of batch analyses for phthalates, polychlorinated biphenyls (PCBs; dioxin-like and non dioxin-like (NDL)), dioxins, furans, and polycyclic aromatic hydrocarbons (PAHs). Some results (i.e., for benzo(a)pyrene, sum of 4 PAHs, and sum of NDL-PCBs) are cited in Table 8 of the notice (p. 20) as well. On p. 19, you note that these results confirm the lack of levels of impurities/contaminants of toxicological concern. We also note that the manufacturing includes a purification step with activated carbon, which would be expected to remove impurities. We do not expect these contaminants to be present in algal oils produced under controlled fermentation. Please clarify why you selected these contaminants for analysis, including how they could be introduced into the algal oil during manufacture.

Response: Like question number 5 above, BASF routinely conducts analyses for many contaminants as the requirements in other countries may require their analysis. We agree that PCBs, PAHs, etc. would not be expected to be present in the DHA algal oil and the analyses for their presence was only conducted for completion of BASF's standard of analysis for oils (e.g., plant sourced oils).

c. You provide results of batch analyses for 2- and 3-monochloro propane diol esters (2- and 3-MCPD). We do not expect 2- and 3-MCPD to be present in algal oils produced under controlled fermentation. Please clarify how these contaminants could be introduced into the algal oil during manufacture, and in particular the high level (436 µg/kg) found in one sample.

Reason: Like question numbers 5 and 6 above, BASF routinely conducts analyses for many contaminants as the requirements in other countries may require their analysis. It is correct that the crude fermented oil does not contain significant traces of such contaminants. However, the refining process involves thermal processing. Under these conditions, such contaminants can be created. BASF has already recognized the possible presence of 3-MCPD esters. Mitigation processes are underway to reduce the formation of these process impurities. However, the product already meets the intended future limits on such contaminants. Suggested limits for 3-MCPD esters within the European Union will be at 500µg/kg for oils used in baby food. However, it is BASF's intention to reduce the presence of 3-MCPD esters to much lower levels.

6. You present the fatty acid profile for your *Schizochytrium* sp. T-18 algal oil in Table 6 (p. 18). However, the values presented in Table 6 are not consistent with that presented in Appendix A pp. 60, 84, and 108. Please clarify the following discrepancies for the record.

Response: The fatty acid data presented in the dossier is based on a test report obtained from a third-party testing lab, RSSL. Unfortunately, the report was not included in the GRAS dossier and is now added for reference to the end of this response.

a. Minor differences in values for fatty acids (e.g., C14:0, C16:1, C20:1, C20:5 (n-3), C22:5 (n-6), and C22:6 (n-3). Are these different data sets?

Response: Yes, they are different data sets; the data in the GRN tables represent analyses by the lab RSSL, while the data in Appendix A represent analyses from BASF internal laboratory testing. As explained above, the RSSL report was inadvertently not included in the GRAS submission but is included at the end of this document.

b. Differences in fatty acids presented in Table 6 vs. Appendix A. The appendix does not include C12:0, C13:0, or C14:1, C15:0, C17:0, C20:3 n-6, while Table 6 includes certain fatty acids (i.e. C22:0, C22:1 n-11, C22:1 n-13, isomers of C22:5, C24:0, and C24:1 n-15) not included in Appendix A. Are these different data sets?

Response: Yes, they are different data sets; the data in the GRN tables represent analyses by the lab RSSL, while the data in Appendix A represent analyses from BASF internal

laboratory testing. As explained above, the RSSL report was inadvertently not included in the GRAS submission but is included at the end of this document.

c. The values for oleic acid (C18:1 n-9) and C18:1 total (oleic plus cis-vaccenic acid) cited in Appendix A do not match the oleic acid values cited in Table 6. While the values in the appendix suggest that the cis-vaccenic isomer predominates, the Table 6 values suggest the opposite. Please clarify this inconsistency.

Response: BASF in-house laboratories separated oleic acid from vaccenic acid in the fatty acid analysis using PhEur as the test method. In the BASF reports, C18:1 is reported as C18:1 oleic acid and C18:1 oleic plus vaccenic acid. Other labs/test methods might not separate these isomers. In the report of RSSL, both C18:1 cis and C18:1 trans are reported. The value reported by RSSL for C18:1 cis should represent the sum of oleic and of vaccenic acid. Whereas the value reported by RSSL for C18:1 trans represents artificial trans isomers due to thermal processing (0-0.1%). The fatty acid report of GRN 677 reported both fatty acids in one number, probably due to the missing resolution of the analytical test method.

d. There are no values for fatty acids in Appendix A for algal oil lot 0016888247.

Response: The values for fatty acids (and sterols) for lot DHA algal oil lot number 0016888247 are attached to the back of this document.

e. If corrections are needed in Table 6, please provided a corrected version of Table 6 (that includes cis-vaccenic acid) for the record.

Response: The attached RSSL laboratory report provides the relevant documentation for the fatty acid data presented in Table 6.

7. You present the sterol content and sterol isomer profile for your *Schizochytrium* sp. T-18 algal oil in Table 7 (p. 19). However, the values presented in Table 7 are different from the values presented in Appendix A pp. 59, 83, and 107. The values differ slightly in sterols reported and % of individual sterols. We request that you clarify the following discrepancies for the record.

Response: Similar to the fatty acid questions above, the data for the sterols is contained in the attached laboratory report of RSSL.

a. None of the values for individual sterols in Table 7 match the sterol values for the same respective lots given in the appendix. Are these different data sets?

Response: Yes, see above response.

b. There are no values for sterols in the appendix for algal oil lot 0016888247.

Response: The values for sterols for lot DHA algal oil lot number 0016888247 are attached to the back of this document.

c. If corrections are needed in Table 7, please provided a corrected version of Table 7 (that includes 24-methylene cholesterol and campestanol) for the record.

Response: The attached RSSL laboratory report provides the relevant documentation for the fatty acid data presented in Table 7. We have added data for 24-methylene cholesterol and campestanol to the table below which represents a revised Table 7 (including relevant GRN 677 sterol range data.

d. Please compare the sterol content of your algal oil with the GRN 677 algal oil.

Parameter	**DHA Algal Oil**				
	DH5750	**DH5751**	**DH5752**	**0016888247**	**GRN 677 Range**
Cholesterol (%)	13.1	13.7	11.7	29.8	12.6 – 32.9
Brassicasterol (%)	5.6	4.0	6.3	3.9	<0.1 – 6.5
Campesterol (%)	3.8	4.2	3.4	4.8	1.2 – 3.9
24-Methylene Cholesterol (%)	2.4	2.6	2.6	Not reported	2.3 - 7.1
Campestanol (%)	<0.1	<0.1	<0.1	0.5	<0.1
Stigmasterol (%)	19.6	14.1	24.0	13.7	<0.1 – 23.1
Delta-7-Campesterol (%)	0.3	0.9	0.4	0.5	<0.1 – 7.0
Delta-5,23 Stigmastadienol (%)	1.6	1.3	1.7	0.9	<0.1 – 7.7
Chlerosterol (%)	20.3	15.8	17.0	9.6	6.3 – 19.3
Beta-Sitosterol (%)	14.8	16.0	19.1	21.1	9.4 – 14.8
Beta-Sitostanol (%)	-	-	-	2.4	<0.1
Delta-5 Avenasterol (%)	1.3	2.9	3.2	1.4	1.2 – 5.7
Delta-5,24 Stigmastdienol (%)	8.9	10.4	6.0	5.2	3.9 – 7.0
Delta-7 Stigmastenol (%)	7.3	13.1	5.2	5.1	<0.1 – 26.1
Delta-7 Avenasterol (%)	3.3	3.7	1.9	1.6	1.4 – 9.1
Total sterols (mg/kg)	705	1020	1210	2843	831 - 2310

8. In your notice you have stated that stability testing was ongoing at the time of submission, and that results were expected by March 2019. Please provide an update on the results of stability testing to confirm the storage conditions that you propose in GRN 862.

Response: Updated stability testing results are attached to the back of this document.

9. On page 27 of the notice (Table 10), you state that the algal oil discussed in GRN 677 contains 40% DHA. Please note that the correct DHA content is ≥35% for GRN 677 (see page 23 of GRN 677). Please state whether you concur.

Response: We concur that GRN 677 states the DHA content as ≥35%.

10. On page 29, you state that literature search was "performed to identify safety data on DHA and DHA algal oil through July 2018". Please conduct an updated literature search and state whether you identified any studies that that report safety concerns related to the subject

substances that may contradict your GRAS determination. If so, please discuss this information and state why you still consider your article of commerce to be GRAS under its intended conditions of use.

Response: As requested, an updated literature search was conducted from August 2018 to the present. No preclinical or clinical studies were identified that report safety concerns related to the subject substances and that would alter our GRAS determination.

11. On page 30, for the Schmitt *et al.* (2012b) study, please state the NOAEL value for F1 females in mg/kg bw/day. (Note: all other NOAELs were also provided in units of mg/kg bw/day for this study. FDA needs NOAELs in expressed in mg/kg bw/day in order to be able to compare these values to the estimated dietary intakes for the article of commerce during its review).

Response: The original WIL Labs report was reviewed and the NOAEL for F1 females was the 25,000ppm algal oil group; equivalent to 2065 mg/kg bw/day.

12. On page 33, you summarize the "Wilbert *et al.*, 1997" study (please note the typo as the correct citation is Wibert *et al*., 1997). We concur that the correct citation is Wibert et al. as correctly stated in the reference list.

a. You state that the test article in this study was "DHA-rich oil from *C. cohnii*". According to the article, the test article was a blend of high-DHA algal oil from *C. cohnii* and a high-ARA fungal oil from *Mortierella alpine.*" Please state whether you concur.

Response: We concur.

b. You state that the doses for DHA-rich algal oil ranged from 210 to 1180 mg/kg bw/day. According to the article, diets were prepared to provide an "oil blend test material" (i.e. a blend of algal and fungal oil (see above)) "at doses of 18 (T18), 60 (T60), and 120 g/kg diet (T120)". Please explain clearly how you calculated a dose range of 210 to 1180 mg DHA-rich algal oil/kg bw/day from the above dietary concentrations for the blend.

Response: Following a review of the Wibert et al. (1997) paper, the doses stated for the DHA rich algal oil are in error. Based on our current review, given a 1:2 blend of DHA to ARA and the DHA plus ARA intake data reported in Table 3, the lowest mean intake was 1.2 g/kg bw/day DHA+ARA and the highest was 13.1 g/kg bw/day DHA+ARA. Given the 1:2 ratio of DHA to ARA, the actual intakes of DHA would range from approximately 400 to 4330 mg/kg bw/day.

13. On page 34, for the Burns *et al.* (1999) study, you state that "DHA-rich oil (DHA-Arachidonic Acid (ARA) blend) from *C. cohnii* was administered in the diet to … rats for 13 weeks. … Doses ranged from 410 to 3290 mg/kg bw/day." According to the article "Mean actual test material intake ranged from 1.1 to 8.2 g/kg/day for males and 1.2 to 8.9 g/kg/day for

females." (See Table 4 in the article.) Please explain clearly where the dose range of 410 to 3290 mg/kg bw/day comes from.

Response: The calculated dose range assumed a 1:2 ratio of DHA to ARA in the blend as stated in the test materials section on page 24 of the article.

14. On page 34, for the Blum *et al*. (2007a) study, you state that "DHA-rich oil (from *Ulkenia sp.* algae) was administered…". According to the article, the test articles were "various combinations of DHA-algal oil and DHA-fish oil" and the "combinations of DHA-algal oil/DHA-fish oil were 0/2000 (DHA-fish oil group), 500/1500 (500 mg/kg group), 1000/1000 (1000 mg/kg group), and 2000/0 mg/kg body weight/day (2000 mg/kg DHA-algal oil group)." Please state whether you concur.

Response: We concur.

15. On page 34, for the Hammond *et al.* (2001b) study, you state that rats were administered "doses ranging from 130 to 5625 mg DHA/kg bw/day for 13 weeks".

a. According to the article, the mean intake was 33 to 1512 mg DHA/kg bw/day in F0 males, 40 to 1680 mg DHA/kg bw/day in F0 females (see start of Results section in the article). Please explain where the dose range of 130 to 5625 mg DHA/kg bw/day comes from.

Response: The study summary is incorrect, and the mean intakes are as stated in your question 15.a above.

b. According to the article, "F0 males were treated for 70 days prior to mating, during mating, and for approximately 3 weeks following mating. F0 females were treated for 2 weeks prior to mating, during mating, and throughout gestation and lactation." Please state the correct duration of the study in units of weeks for males and females.

Response: Likewise, the duration of the study in incorrectly stated. The duration of the study was the following: "F0 males were treated for 70 days prior to mating, during mating, and for approximately 3 weeks following mating. F0 females were treated for 2 weeks prior to mating, during mating, and throughout gestation and lactation."

16. On page 35, for the Arterburn *et al*. (2000b) study, you state that "DHA-rich oil from *C. cohnii*" (i.e. DHASCO) "was administered by oral gavage … at doses ranging from 260 to 645 mg/kg bw/day". According to the article "test material doses of 500 or 1250 mg/kg body weight/day of DHASCO (low and high DHASCO groups, respectively) were prepared". As the article states that the DHASCO used contains 51.7% DHA, it seems that the dose range of 260 to 645 mg/kg bw/day is for the intake of DHA and not for the intake of DHASCO. Please confirm.

Response: That is correct. The stated dose range is for DHA and not for DHASCO.

17. On page 35, for the Falk *et al.* (2017) study, in the results section, you state that "the NOAELs for DHA and ARA in both studies were 5000 mg/kg bw/day". For clarity, please note

that these NOAELs were for DHA-rich algal oil and ARA-rich fungal oil not for DHA and ARA. Please state whether you concur.

Response: We concur, the NOAELs were for DHA-rich algal oil and ARA-rich fungal oil, not for DHA and ARA. The DHA content of the DHA-rich algal oil was approximately 41%.

18. On page 37, for the Fedorova-Dahms *et al*. (2014) study, the dose levels were not stated. Please state the dose levels using units of mg/kg bw/day. Please note NOAEL, if any.

Response: The test articles were added to formula at concentrations of 0.32% and 0.96% DHA (% of total fatty acids). The dose volume was 500 mL/kg bw/day. The DHA source concentration was either 230 or 700 mg/L. The authors did not report the DHA dose levels in mg/kg bw/day; but given that the piglets ranged in weight from 1.7 – 2.7 kg at randomization (for purposes of this calculation 2.0 kg), a 2 kg piglet would have received DHA doses of approximately 115 mg DHA/kg bw/day or 350 mg DHA/kg bw/day. A NOAEL was not stated by the authors, but no treatment-related adverse effects were noted at either concentration or estimated dose level.

19. On page 37, for the Huang *et al.* (2002) and the Abril *et al*. (2003) studies, state the approximate intake levels in units of mg DHA/kg bw/day.

Response: The authors only estimated the intake level of DHA in units of mg/kg/day for the high dose group. The approximate DHA intake of the high-dose group ranged from approximately 210 -290 mg DHA/kg/day with the lowest value representing intake towards the end of the study at 25 days of life. Given the dose groups were selected to be at 1x, 2x, and 5x intervals, the low and mid DHA intake dose ranges would be approximately 42 – 59 mg DHA/kg/day for the low-dose group and 84 – 118 mg DHA/kg/day for the mid-dose group.

20. Please provide the full reference for the EFSA (2012) Panel conclusions (see EFSA Journal).

Response: EFSA. 2012. Scientific opinion on the tolerable upper intake level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA). EFSA Journal 10(7):2815.

21. On pages 29 and 45, you state that "Numerous studies have been conducted … including … carcinogenicity …". Please identify (i.e. provide references for) this/these carcinogenicity study(ies).

Response: We concur and agree that the reference to carcinogenicity studies is in error and should be deleted.

22. On page 40, you state that "the studies reviewed in these notifications support the safe use of DHA in infant formula up to 1% of total fatty acids". Please state what this level is using units of mg DHA/kg bw/day so comparison to the proposed use level of 27 to 33 mg/kg bw/day (page 48) can be made.

Response: The sentence should read 1% of total fat rather than 1% of total fatty acids. Therefore, the 1% total fat intake would represent approximately 54 – 66% mg/kg bw/day.

23. On page 6, you state that the article of commerce is "intended for use as direct food ingredients in 1) foods and 2) non-exempt and pre-term exempt infant formula…". However, on page 23-24 you state, "Therefore, BASF's DHA ingredients could be used in any exempt (pre-term or term) or non-exempt formula that contains DHA" and, "DHA algal oil and the encapsulated powder form are intended for use as direct ingredients in exempt (pre-term or term) and non-exempt (term) infant formula…". Please clarify for exempt and non-exempt infant formula whether the intended population is pre-term infants, term infants, or both pre-term and term infants.

Response: The intended use for the DHA algal oil ingredient is non-exempt (term) and exempt (preterm) infant formula.

24. Please clarify the intended protein source/sources (e.g. milk, soy, whey, etc.) for the infant formulas that the ingredient would be added to.

Response: BASF is only the manufacturer of the DHA algal oil ingredient and does not manufacture infant formula. However, similar to GRN 677, the proposed DHA algal oil will be used with milk- and soy-based formulas.

25. On page 24, you state: "Assuming incorporation of the proposed DHA ingredient at a maximum use level of 0.5% of total fat, the intake of DHA would be 27-33 mg/kg bw/day." Please state whether "0.5% of total fat" is the intended maximum use level of the substance in infant formula. If so, please include this information in the "Intended Use in Food" section of the notice.

Response: "0.5% of total fat" is the intended maximum use level of the substance in infant formula and is hereby noted in Part 3 on Dietary Exposure and Use in Infant Formula.

Please note that FDA does not consider the efficacy of ingredients added to food to treat diseases or health conditions. If an efficacy study is cited in a GRN, you may discuss the safety data (only) in your narrative. For example, the efficacy data from the Turk *et al.* (2013) study does not belong to the section titled "additional safety-related study" because you did not report any safety-related data for this study, only efficacy outcomes.
Response: We acknowledge that the study should not have been include in the GRN.

Additionally, on page 27 (& pp. 45 & 48), you state that "Two other GRAS notifications (GRNs 731, 732) for DHA-rich oils from microalgae are pending (FDA 2017a; 2017b)." Please note that GRNs 731 and 732 have been completed and each received a no questions letter from FDA on April 6, 2018. (See FDA GRAS inventory online.).

Response: We acknowledge that GRNs 731 and 731 are now complete and each have received a no questions letter from FDA on April 6, 2018.

Certificate of Analysis

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-1** Your Refs: 96914 DH 5750
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C12:0	0.8	%
	C13:0(I)	0.1	%
	C14:0	9.1	%
	C14:1	0.1	%
	C15:0	0.4	%
	C16:0	20.8	%
	C16:1	4.1	%
	C17:0	0.1	%
	C18:0	0.7	%
	C18:1(trans)	0.1	%
	C18:1(cis)	7.0	%
	C18:2(cis)	0.5	%
	C18:3(alpha)	0.2	%
	C20:0	0.1	%
	C20:1	0.4	%
	C22:1	0.5	%
	C24:0	0.1	%
	C20:3 (n6)	0.1	%
	C20:4 (n6)	0.3	%
	C20:5 (n3)	1.6	%
	C22:6 (n3)	44.5	%
	C22:5 (n6)	8.1	%
	C22:5 (n3)	0.3	%

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Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-1** Your Refs: 96914 DH 5750
Description: DHA Algal Oil

Method	Analysis	Result	Units
Normalised fatty acid profile (%).			
TM-331	alpha tocopherol	550	mg/kg
TM-331	beta tocopherol	92	mg/kg
TM-331	gamma tocopherol	1544	mg/kg
TM-331	delta tocopherol	817	mg/kg
TM-331	Total Tocopherols	3003	mg/kg

Tocopherols were determined by HPLC with a fluorescence detector using a method based on ISO 9936 :2016.

TM-252	Cholesterol	13.1	%
TM-252	Brassicasterol	5.6	%
TM-252	Campesterol	3.8	%
TM-252	Stigmasterol	19.6	%
TM-252	Δ-7-Campesterol	0.3	%
TM-252	Δ-5, 23-Stigmastadienol	1.6	%
TM-252	Chlerosterol	20.3	%
TM-252	β-Sitosterol	14.8	%
TM-252	Δ-5-Avenasterol	1.3	%
TM-252	Δ-5,24-Stigmastadienol	8.9	%
TM-252	Δ-7-Stigmastenol	7.3	%
TM-252	Δ-7-Avenasterol	3.3	%
TM-252	Total Sterols	705	mg/kg

Total sterols were determined by Gas Chromatography using a method based on the Official Journal of the European Communities method for analysis of sterols in olive oil. Very low levels of sterols were detected in the samples.

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Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-1** Your Refs: 96914 DH 5750
Description: DHA Algal Oil

Method	Analysis	Result	Units
	EPA	15.4	mg/g
	EPA	15.1	mg/g
	DHA	430.6	mg/g
	DHA	430	mg/g

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Report No: P18-02696
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Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-2** Your Refs: 96915 DH 5751
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C12:0	0.9	%
	C13:0(I)	0.1	%
	C14:0	9.7	%
	C15:0	0.5	%
	C16:0	22.3	%
	C16:1	2.9	%
	C17:0	0.2	%
	C18:0	0.8	%
	C18:1(cis)	6.1	%
	C18:2(cis)	0.6	%
	C18:3(alpha)	0.2	%
	C20:0	0.1	%
	C20:1	0.4	%
	C22:1	0.5	%
	C24:0	0.1	%
	C20:3 (n6)	0.1	%
	C20:4 (n6)	0.3	%
	C20:5 (n3)	1.7	%
	C22:6 (n3)	44.2	%
	C22:5 (n6)	7.8	%
	C22:5 (n3)	0.4	%
Normalised fatty acid profile (%).			
TM-331	alpha tocopherol	536	mg/kg

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-2** Your Refs: 96915 DH 5751
Description: DHA Algal Oil

Method	Analysis	Result	Units
TM-331	beta tocopherol	93	mg/kg
TM-331	gamma tocopherol	1395	mg/kg
TM-331	delta tocopherol	743	mg/kg
TM-331	Total Tocopherols	2767	mg/kg

Tocopherols were determined by HPLC with a fluorescence detector using a method based on ISO 9936 :2016.

TM-252	Cholesterol	13.7	%
TM-252	Brassicasterol	4.0	%
TM-252	Campesterol	4.2	%
TM-252	Stigmasterol	14.1	%
TM-252	Δ-7-Campesterol	0.9	%
TM-252	Δ-5, 23-Stigmastadienol	1.3	%
TM-252	Chlerosterol	15.8	%
TM-252	β-Sitosterol	16.0	%
TM-252	Δ-5-Avenasterol	2.9	%
TM-252	Δ-5,24-Stigmastadienol	10.4	%
TM-252	Δ-7-Stigmastenol	13.1	%
TM-252	Δ-7-Avenasterol	3.7	%
TM-252	Total Sterols	1020	mg/kg

Total sterols were determined by Gas Chromatography using a method based on the Official Journal of the European Communities method for analysis of sterols in olive oil. Very low levels of sterols were detected in the samples.

	EPA	16.2	mg/g
	EPA	16.4	mg/g

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-2** Your Refs: 96915 DH 5751
Description: DHA Algal Oil

Method	Analysis	Result	Units
	DHA	428.2	mg/g
	DHA	428.2	mg/g

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-3** Your Refs: 96916 DH 5752
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C12:0	0.9	%
	C13:0(I)	0.1	%
	C14:0	9.8	%
	C14:1	0.1	%
	C15:0	0.3	%
	C16:0(I)	0.1	%
	C16:0	18.5	%
	C16:1	6.6	%
	C17:0	0.1	%
	C18:0	0.7	%
	C18:1(trans)	0.1	%
	C18:1(cis)	10.3	%
	C18:2(cis)	0.5	%
	C18:3(alpha)	0.2	%
	C20:0	0.1	%
	C20:1	0.6	%
	C22:1	0.4	%
	C24:0	0.1	%
	C20:3 (n6)	0.1	%
	C20:4 (n6)	0.2	%
	C20:5 (n3)	1.5	%
	C22:6 (n3)	41.1	%
	C22:5 (n6)	7.2	%

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-3** Your Refs: 96916 DH 5752
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C22:5 (n3)	0.3	%
Normalised fatty acid profile (%).			
TM-331	alpha tocopherol	530	mg/kg
TM-331	beta tocopherol	90	mg/kg
TM-331	gamma tocopherol	1504	mg/kg
TM-331	delta tocopherol	775	mg/kg
TM-331	Total Tocopherols	2899	mg/kg
Tocopherols were determined by HPLC with a fluorescence detector using a method based on ISO 9936 :2016.			
TM-252	Cholesterol	11.7	%
TM-252	Brassicasterol	6.3	%
TM-252	Campesterol	3.4	%
TM-252	Stigmasterol	24.0	%
TM-252	Δ-7-Campesterol	0.4	%
TM-252	Δ-5, 23-Stigmastadienol	1.7	%
TM-252	Chlerosterol	17.0	%
TM-252	β-Sitosterol	19.1	%
TM-252	Δ-5-Avenasterol	3.2	%
TM-252	Δ-5,24-Stigmastadienol	6.0	%
TM-252	Δ-7-Stigmastenol	5.2	%
TM-252	Δ-7-Avenasterol	1.9	%
TM-252	Total Sterols	1210	mg/kg

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email: enquiries@rssl.com
web: www.rssl.com

Certificate of Analysis

Ms Edith Von Kries
Cognis GmbH & Co.KG
Standort Illertissen
1 Robert-Hansen-Strasse
D- 89257 Illertissen
Germany

Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-3** Your Refs: 96916 DH 5752
Description: DHA Algal Oil

Method	Analysis	Result	Units
	Total sterols were determined by Gas Chromatography using a method based on the Official Journal of the European Communities method for analysis of sterols in olive oil. Very low levels of sterols were detected in the samples.		
	EPA	14.3	mg/g
	EPA	14.6	mg/g
	DHA	394.4	mg/g
	DHA	394.8	mg/g

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-4** Your Refs: 96917 0016888247
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C12:0	1.0	%
	C13:0(I)	0.1	%
	C13:0	0.1	%
	C14:0	10.2	%
	C14:1	0.1	%
	C15:0	0.5	%
	C16:0	22.3	%
	C16:1	3.9	%
	C17:0	0.2	%
	C18:0	0.8	%
	C18:1(cis)	7.1	%
	C18:2(cis)	0.6	%
	C18:3(alpha)	0.2	%
	C20:0	0.1	%
	C20:1	0.5	%
	C22:1	0.5	%
	C24:0	0.1	%
	C20:3 (n6)	0.1	%
	C20:4 (n6)	0.3	%
	C20:5 (n3)	1.7	%
	C22:6 (n3)	41.7	%
	C22:5 (n6)	7.7	%
	C22:5 (n3)	0.3	%

Science With Service

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-4** Your Refs: 96917 0016888247
Description: DHA Algal Oil

Method	Analysis	Result	Units
Normalised fatty acid profile (%).			
TM-331	alpha tocopherol	484	mg/kg
TM-331	beta tocopherol	84	mg/kg
TM-331	gamma tocopherol	1573	mg/kg
TM-331	delta tocopherol	693	mg/kg
TM-331	Total Tocopherols	2833	mg/kg
Tocopherols were determined by HPLC with a fluorescence detector using a method based on ISO 9936 :2016.			
TM-252	Cholesterol	29.8	%
TM-252	Brassicasterol	3.9	%
TM-252	Campesterol	4.8	%
TM-252	Stigmasterol	13.7	%
TM-252	Δ-7-Campesterol	0.5	%
TM-252	Δ-5, 23-Stigmastadienol	0.9	%
TM-252	Chlerosterol	9.6	%
TM-252	β-Sitosterol	21.1	%
TM-252	Sitostanol	2.4	%
TM-252	Δ-5-Avenasterol	1.4	%
TM-252	Δ-5,24-Stigmastadienol	5.2	%
TM-252	Δ-7-Stigmastenol	5.1	%
TM-252	Δ-7-Avenasterol	1.6	%
TM-252	Total Sterols	2843	mg/kg

Total sterols were determined by Gas Chromatography using a method based on the Official Journal of the European Communities method for analysis of sterols in olive oil.

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-4** Your Refs: 96917 0016888247
Description: DHA Algal Oil

Method	Analysis	Result	Units
	EPA	16.1	mg/g
	EPA	16.1	mg/g
	DHA	397.1	mg/g
	DHA	398	mg/g

EPA & DHA were determined using a method based on EP method 2.4.29 and the levels were calculated as mg/g and reported as triglycerides.

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BASF
We create chemistry

Order-No. : 95351

Analysis Report

Product	**DHA Algal Oil**
ART	**DHA rich Oil from microalgae Schizochytrium sp.**
Lot No.	**0016888247, prod: 2017.03.16 analysis: 2017.09.08**

C14:0	9,8	Area-%
C16:0	22,1	Area-%
C16:1 c9	4,0	Area-%
C18:0	0,8	Area-%
C18:1c9	1,8	Area-%
C18:1 (Sum)	7,4	Area-%
C18:2 c9,c12	0,6	Area-%
C18:3 c9,c12,c15	0,2	Area-%
C18:4 c6,c9,c12,c15	0,3	Area-%
C20:0	<0,1	Area-%
C20:1 (Sum)	<0,05	Area-%
C20:4	0,3	Area-%
C20:5	2,1	Area-%
C21:5 c18	< 0,1	Area-%
C22:0	< 0,1	Area-%
C22:1 c11	<0,05	Area-%
C22:5 c16	7,7	Area-%
C22:5 c19	1,3	Area-%
C22:6	42,0	Area-%
C24:0	<0,05	Area-%
C24:1 c15	0,1	Area-%
C20:5 as TG	20	mg/g
C22:6 as TG	404	mg/g
trans fatty acids (Sum C18/C20:5/C22:6)	0,1	Area-%
Total sterols	0,5	Weight-%
Cholesterol	22,6	Area-%
Brassicasterol	3,3	Area-%
Campesterol	3,6	Area-%
Campestanol	0,5	Area-%
Stigmasterol	8,3	Area-%
ß-Sitosterol	18,5	Area-%
ß-Sitostanol	1,2	Area-%
d5-Avenasterol	3,5	Area-%
d7-Stigmastenol	10,1	Area-%
d7-Avenasterol	2,8	Area-%

Sum of other sterols	25,6 04.09.2017	Area-%

Fatty acid distribution: IA-017055-IA-055055; Sterol content and sterol distribution: IA-000014 mod. (GC-FID)

Illertissen, 15.09.2017

BASF Personal Care and Nutrition GmbH
Location Illertissen

(b) (6)

Dr. E. v. Kries
QC, Head of laboratory

Stability data

Version 4, 04.2019

DHA Algal Oil

PRD no. 30599327
Manufacturing site: BASF Personal Care and Nutrition GmbH, Illertissen, Germany

Storage conditions and stability study information:
Stability tests for DHA Algal Oil produced in commercial scale have been started in March 2017.
The storage test is carried out at the following defined climatic
conditions:
≤ -18°C
+2 to +8°C

The ongoing stability test is presented below. This data provides the justification for the stated shelf life of DHA Algal Oil.

Analytical method:
Please refer to the table below.

Packaging:
The stability test is conducted on product packaged in a 25kg metal drum, same as the primary packaging material used for storage and distribution of the 25kg sales product. This packaging is also of an equivalent quality compared to the 190kg metal drum sales article.

Test attributes:
The stability study includes testing of those attributes that are susceptible to change during storage and is likely to influence the quality, safety and/or efficacy.

Long term stability study (ongoing):
DHA Algal Oil at ≤ -18°C (**m**: months); Lot 0016888247; Test start: 13.03.2017

Parameter	Specification	Unit	Method	Start	6 m	12 m	18 m	24 m
Appearance	Clear to turbid, yellow to orange liquid		AX-001001	conforms	conforms	conforms	conforms	conforms
Acid value	≤ 0.5	mgKOH/g	ISO 660	0.1	0.1	0.1	0.1	0.1
Peroxide value	≤ 4.0	meq O/kg	CP-001009	0.1	0.4	0.5	0.4	0.6
Anisidine value	≤ 15	-	ISO 6885	2.5	2.8	2.7	2.7	2.7
DHA as TG	≥ 380	mg/g	PhEur 2.4.29	403	413	401	409	408
Total tocopherols	No limit	mg/kg	IA-005034	2993	3011	3088	3036	3033
Total aerobic plate count	Max. 1000	cfu/g	MB-002035	<10	-	-	-	<10
Yeast and mould	Max. 100	cfu/g	MB-002039	<10	-	-	-	<10
Enterobacteria	Neg/10g		MB-008052	negative	-	-	-	negative
Salmonella	Neg/25g		MB-001053	negative	-	-	-	negative

Long term stability study (ongoing):
DHA Algal Oil at +2 to +8°C (**m**: months); Lot 0016888247; Test start: 13.03.2017
*outlier result, sample drawn from top of drum slightly up-concentrated in DHA and tocopherols

Parameter	Specification	Unit	Method	Start	6 m	12 m	18 m	24 m
Appearance	Clear to turbid, yellow to orange liquid		AX-001001	conforms	conforms	conforms	conforms	conforms
Acid value	≤ 0.5	mgKOH/g	ISO 660	0.1	0.1	0.1	0.1	0.1
Peroxide value	≤ 4.0	meq O/kg	CP-001009	0.1	0.9	0.5	2.8	3.7
Anisidine value	≤ 15	-	ISO 6885	2.5	2.6	2.0	3.0	3.1
DHA as TG	≥ 380	mg/g	PhEur 2.4.29	403	417	436*	425	435
Total tocopherols	No limit	mg/kg	IA-005034	2993	3051	3453*	3209	3331
Total aerobic plate count	Max. 1000	cfu/g	MB-002035	<10	-	-	-	<10
Yeast and mould	Max. 100	cfu/g	MB-002039	<10	-	-	-	<10
Enterobacteria	Neg/10g		MB-008052	negative	-	-	-	negative
Salmonella	Neg/25g		MB-001053	negative	-	-	-	negative

Conclusion:

Ongoing stability test has shown that this product is stable for at least 24 months,
when it is stored in the original unopened container at frozen conditions of ≤ -18°C, respectively +2 to +8°C.

The above listed data demonstrates that DHA Algal Oil is justified for the following stability in the original unopened container:

- At refrigerated conditions of +2 to +8°C the product is stable for min. 12 months.
- At frozen conditions at ≤ -18°C the product will keep for min. 24 months.

From:	Don Schmitt
To:	Downey, Jason
Cc:	Haresh P Madeka; Juergen Gierke; Herbert Roth
Subject:	Re: GRN 862 - BASF DHA Algal Oil - Additional Follow-Up Questions
Date:	Thursday, October 31, 2019 12:44:40 PM
Attachments:	image002.png FDA Q&A BASF GRN 862 103119.pdf

Dear Dr. Downey,

We have attached responses to all of the follow up questions raised by FDA in your email dated October 18, 2019. Please let me know if you have any further needs.

Best regards,

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540
phone: 630.352.0303
email: dschmitt@toxstrategies.com

From: "Downey, Jason" <Jason.Downey@fda.hhs.gov>
Date: Friday, October 18, 2019 at 2:39 PM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 862 - BASF DHA Algal Oil - Additional Follow-Up Questions

Dear Mr. Schmitt,

1. Please provide Safety Data Sheets for BASF's DHA algal oil and DHA algal oil powder.

   Answer: Please see attachment for Safety Data Sheets for DHA algal oil and powder products.

2. We requested that you address the observed differences in fatty acid content between your *Schizochytrium* sp. T-18 algal oil and the levels specified in the Food Chemicals Codex (FCC 11, 2019) monograph for *Schizochytrium* sp. algal oil. In response, you provided a data table to compare fatty acid compositions and stated: "It is the opinion of BASF that the slight variation in fatty acid content compared to the FCC specifications has no appreciable effect on the quality or safety of the proposed docosahexaenoic acid (DHA) algal oil for use in food and infant formula." We presume this statement is based on the similarity of BASF's DHA algal oil to oils that have been the subject of published safety studies (e.g., *Schizochytrium* sp. T-18 algal oil that is the subject of GRN 677), known variation in levels of fatty acids resulting from optimization of DHA production, or other factors. However, you do not provide information to support this statement and we request that you briefly state the basis for your opinion for the GRN record.

   Answer: The FCC monograph for *Schizochytrium* sp algal oil is based on one specific *Schizochytrium* strain from one specific supplier. Other algal oils with different fatty acid profiles compared to the FCC monograph have been authorized previously for use in infant formula in GRNs 553, 677, 776, and 777. FDA has recognized minor variations from the FCC monograph in the "No Questions" letter for GRN 776. Minor difference in the fatty acid profile can be attributed to the organism strain of the *Schizochytrium* algae.

3. In your response to question one of FDA's questions sent to you on September 19, 2019, you note that in the future, an algal oil of lower DHA concentration (e.g., 35% DHA) may be manufactured and used in infant formula. Please clarify if this change would arise from blending with a non-DHA containing oil or from a predictable change in the method of manufacture. If the latter, please provide a brief statement or reference regarding variation in levels of DHA with fermentation conditions or other relevant change in manufacture.

   Answer: After reconsideration, BASF has no intention to reduce the DHA content in the proposed algal oil.

4. You note the enzyme used in the method of manufacture is the same as that used in GRNs 677 and 533. Please confirm that the enzyme is a protease preparation produced by *Bacillus licheniformis*, that the enzyme is food grade and complies with specifications established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2006) and FCC 11 (2019) for food grade enzymes, and that the enzyme is not present in the final algal oil product.

   Answer: The enzyme is a protease preparation produced by *Bacillus licheniformis*, is food grade and is used in accordance with 21 CFR 184.1027. The enzyme complies with specifications established by the Joint FAO/WHO Expert Committee on Food Additives

(JECFA, 2006) and FCC 11 (2019) for food grade enzymes and is not present in the final algal oil product.

5. We requested that you provide additional information on the method of refining your algal oil. Our question was intended to clarify apparent differences in the method of manufacture between GRNs 677 and 862. While you provide additional details about your method, it is still unclear if this is the same method that was previously described in GRN 677 or if it has been modified. Please identify any differences between the method of manufacture you describe and the method of manufacture used to produce the GRN 677 oil that was the subject of safety studies. If the methods are the same, please provide a statement of clarification.

   Answer: There is no significant conflict or difference between the oil refining process in GRN 677 and GRN 862. GRN 677 expresses clearly that the processing methods are analogue to vegetable oil refining. In the manufacturing flow chart of GRN 677 (see Figure 3 and narrative below), the so called "Degumming Step" is presented in which potential phospholipids are removed by addition of citric or phosphoric acid solutions. In the manufacturing process description, it was clearly expressed that the degumming step was optional because MARA was also aware that their crude oil was very low in such phospholipids and thus doesn't require that this be a mandatory step. As part of BASF's development/validation, it has been proven to produce a consistent quality analogue to GRN677 by intentionally omitting this optional process.

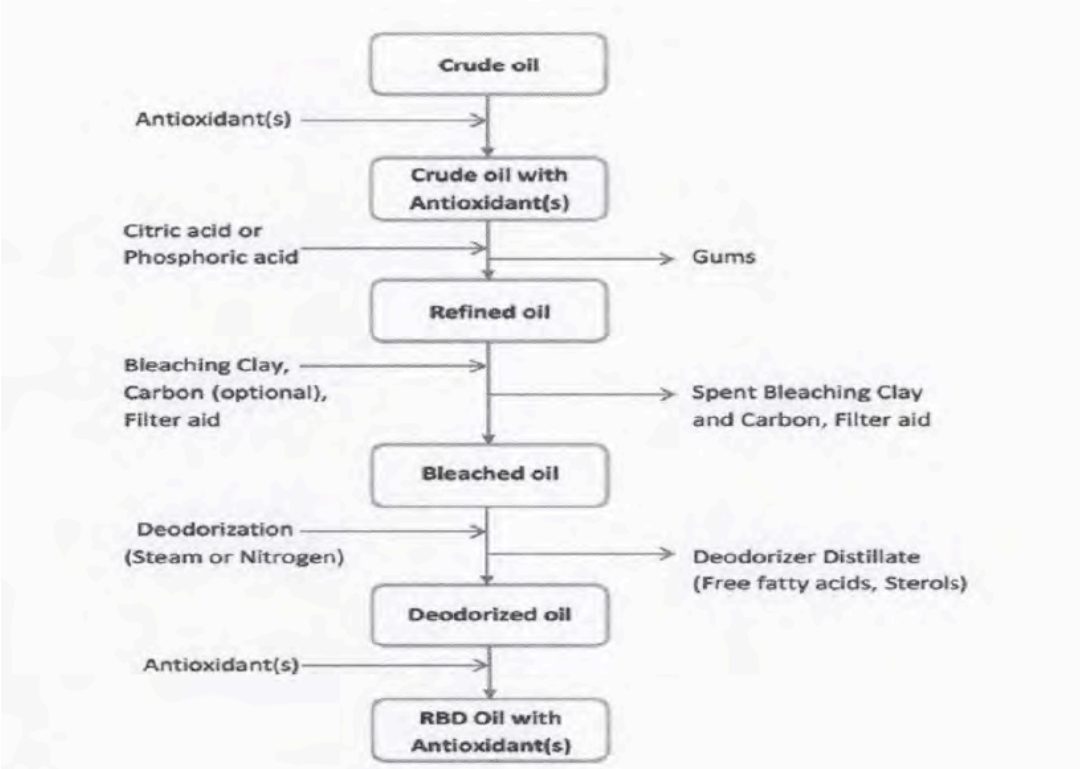

Figure 3. DHA algal oil refining process

An additional optional step that may be employed prior to any of the above steps is fractionation, also known as winterization, in which the semi-solid crude algal oil is cooled and centrifuged or filtered to obtain a crude algal oil that flows easily at room temperature. Winterization can be performed on the crude oil or subsequent to any of the other steps (e.g., after refining, bleaching, deodorization). The resultant fractionated/winterized crude algal oil is a clear liquid at room temperature. Process conditions of the other steps shown in the above flow diagram do not change. Optional steps described below are customer-driven and conducted at a customer's request. The steps in the algal oil refining process are described in more detail in the sections that follow.

Degumming (Optional)

Most crude oils isolated from natural sources contain gums, which after separation from the oil, primarily consist of phospholipids, some entrained oil, traces of soluble sugars, and solid particles. Some of the phospholipids become hydrated and oil-insoluble.

12

12

6. You provide a statement about levels of 3-monochloropropane-1,2-diol (3-MCPD) esters in your algal oil and indicate that "mitigation processes are underway to reduce the formation of these process contaminants." Please provide additional information to support this statement, including reference to industry methods suitable for reduction of 3-MCPD in omega-3 long chain polyunsaturated fatty acid (LCPUFA) oils.

   Answer: 3-MCPD esters can be formed from precursors during higher temperature refining of food oils. Diglycerides which are present in algal oil as well as in fish oils are such precursors for 3-MCPD esters. BASF follows the attached mitigation strategy of Codex specifically through the adjustment of the bleaching conditions.

7. In response to our Question 12b, which referenced the study Wilbert *et al*. (1997), you state that "Given the 1:2 ratio of DHA to ARA, the actual intakes of DHA would range from approximately 400 to 4330 mg/kg bw/day." Please note that this range is for the intake of DHA-rich algal oil and not for DHA. Please state whether you concur.

   Answer: We concur.

8. Regarding the study Burns et al. (1999) referenced in our Question 13, please note that as stated in the original question by FDA "Mean actual test material intake ranged from 1.1 to 8.2 g/kg/day for males and 1.2 to 8.9 g/kg/day for females." (See Table 4 in the article.) Hence, the overall range for the blend was 1.1 to 8.9 g/kg/day. Assuming a 1:2 for DHA-rich oil to ARA-rich oil, this range translates to 367 to 2,967 mg DHA-rich oil/kg bw/day. Please state whether you concur, and if not, explain how you calculated a range of 410 to 3290 mg/kg bw/day.

   Answer: We concur.

9. Regarding the study Hammond *et al.* (2001b) referenced in our Question 15b, please calculate the *total* number of weeks males and females were treated for.

   Answer: F_0 males, 15 weeks (10 weeks pre-mating period, 2 weeks mating period, 3 weeks post mating period); F_0 females, 7 weeks (2 weeks pre-mating period, 2-weeks mating period, 3 weeks post-mating period).

10. In response to our Question 22, which referenced a statement on page 40 of your notice, you state "Therefore, the 1% total fat intake would represent approximately 54 – 66% mg/kg bw/day."
    Please:

    1) clarify what the unit is,

    Answer: mg/kg bw/day

    2) clarify what the substance is,

    Answer: DHA

    3) provide intake level of DHA in units of mg/kg bw/day.

    Answer: 54-66 mg DHA/kg bw/day

    4) compare this intake level of DHA to your proposed DHA intake level (27 to 33 mg DHA/kg bw/day) on page 48 of the notice.

    Answer: The statement on page 40 of the original GRAS notification indicates that the studies in human infants summarized in previous GRNs support the safe use of DHA in infant formula up to 1% of total fatty acids. However, the current GRN provides the assumption of maximum use level of 0.5% of total fat, or approximately 27-33 mg DHA/kg bw/day, below the level supported as safe in previous GRNs.

11. In response to our Question 2, you provided microbiological contaminant limits for the T-18 algal oil, including a limit on *Salmonella* spp. We note that 21 CFR 106.55 specifies limits for *Cronobacter* spp. and *Salmonella* spp. in infant formula. Please provide a limit for *Cronobacter* spp. in the specifications for T-18 algal oil or explain why a specification for *Cronobacter* spp. is not necessary for the T-18 algal oil.

    Answer: The oil had been tested negatively for *Enterobacteria*. *Cronobacter* is contained in the group of *Enterobacteria* and based on the results of this test is not present in the algal oil. Therefore, no specific test for *Cronobacter* spp. had been performed. Furthermore, the algal oil is processed under significant heat (>150°C in the last deodorization step) which can be considered a kill step for *Enterobacteria*. In addition, such oils are processed for infant formula use via a wet processing step which includes emulsification and pasteurization as a killing step of the complete emulsion for product safety. Thus, it can be concluded that BASF

algal oil is safe as it does not contain Enterobacteria . Mandatory pasteurization at the production of infant food formula ensures for the entire safety of the finished formulation.

12. Your cover letter indicates maximum use levels of 1.45% and 0.87% by weight DHA algal oil in meat and poultry respectively. Table 9 of your notice lists maximum use levels of 1.25% and 0.75% by weight DHA oil in meat and poultry products respectively. Please clarify the maximum intended use levels for DHA algal oil in food as served for meat and poultry.

    Answer: Given the listing for algal oil derived from *Schizochytrium* sp. in the USDA/FSIS safe and suitable list which allows addition to meat and poultry at maximum use levels of 1.45% and 0.87% by weight DHA algal oil in meat and poultry, respectively, the maximum intended use is that stated in the safe and suitable list.

13. Please clarify whether DHA algal oil powder is intended for use in meat and poultry products. If DHA algal oil powder is intended for use in meat and poultry products, please provide its functional or technical effect in the food.

    Answer: The DHA algal oil powder is not intended for use in meat and poultry products.

14. Please provide the proportion of formulation ingredients and processing aids present in the final DHA algal oil and DHA algal oil powder products.

    Answer: The complete composition of the DHA algal oil and DHA algal oil powder are attached to this document. Nitrogen for replacing air in the product packaging is the only processing agent that would remain/be in contact with the finished algal DHA products.

15. Please indicate whether your intended use in fish includes fish of the order Siluroformes.

    Answer: While unlikely, it is possible that the DHA ingredient(s) could be used in fish products of the order Siluroformes.

Attachments

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Safety Data Sheet
DHA Algal Oil

1. Identification

Product identifier used on the label

DHA Algal Oil

Recommended use of the chemical and restriction on use
Recommended use*: food additive(s)

* The “Recommended use” identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

Company:
BASF CORPORATION
100 Park Avenue
Florham Park, NJ 07932, USA

Telephone: +1 973 245-6000

Emergency telephone number

CHEMTREC: 1-800-424-9300
BASF HOTLINE: 1-800-832-HELP (4357)

Other means of identification
Synonyms: Blend based on: Docosahexaenoic acid

2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Classification of the product

No need for classification according to GHS criteria for this product.

Label elements

The product does not require a hazard warning label in accordance with GHS criteria.

Hazards not otherwise classified

Mop up spills with non-flammable adsorbents (e.g. vermiculite, spill mats). Soiled textiles / cleaning rags / adsorbents and Silica are capable of self ignition and should be wetted with water and must be disposed of in a safe manner. High risk of slipping due to leakage/spillage of product. The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Under the referenced regulation, this product does not contain any components classified for health hazards above the relevant cut off value.

4. First-Aid Measures

Description of first aid measures

General advice:
Remove contaminated clothing.

If inhaled:
If difficulties occur after vapour/aerosol has been inhaled, remove to fresh air and seek medical attention.

If on skin:
Wash thoroughly with soap and water.

If in eyes:
Wash affected eyes for at least 15 minutes under running water with eyelids held open.

If swallowed:
Rinse mouth and then drink plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms: No significant reaction of the human body to the product known.

Indication of any immediate medical attention and special treatment needed

Note to physician
Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media:
water spray, dry powder, alcohol-resistant foam, carbon dioxide

Unsuitable extinguishing media for safety reasons:
water jet

Special hazards arising from the substance or mixture

Hazards during fire-fighting:
2-propenal, carbon monoxide, carbon dioxide,
The substances/groups of substances mentioned can be released in case of fire. Evolution of fumes/fog. Burning produces harmful and toxic fumes.

Advice for fire-fighters

Protective equipment for fire-fighting:
Wear a self-contained breathing apparatus.

Further information:
In case of combustion evolution of toxic gases/vapours possible. Cool endangered containers with water-spray. Do not spray water directly on fire, product will float and could be reignited on surface of water. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental release measures

Further accidental release measures:
High risk of slipping due to leakage/spillage of product.

Personal precautions, protective equipment and emergency procedures

Use personal protective clothing. Information regarding personal protective measures see, section 8.

Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

Mop up spills with non-flammable adsorbents (e.g. vermiculite, spill mats). Soiled textiles / cleaning rags / adsorbents and Silica are capable of self ignition and should be wetted with water and must be disposed of in a safe manner. Dispose of absorbed material in accordance with regulations.

7. Handling and Storage

Precautions for safe handling

No special measures necessary provided product is used correctly.

Protection against fire and explosion:
Take precautionary measures against static discharges. Avoid all sources of ignition: heat, sparks, open flame. Soiled textiles / cleaning rags / adsorbents and Silica are capable of self ignition and should be wetted with water and must be disposed of in a safe manner.

Conditions for safe storage, including any incompatibilities

Suitable materials for containers: glass, Stove-lacquer R 78433, Aluminium

Further information on storage conditions: Keep only in the original container. Keep container tightly closed and dry; store in a cool place. Keep away from heat. Protect contents from the effects of light. Keep under nitrogen.

8. Exposure Controls/Personal Protection

No occupational exposure limits known.

Personal protective equipment

Respiratory protection:
Respiratory protection in case of vapour/aerosol release.

Hand protection:
Wear impermeable chemical resistant protective gloves.

Eye protection:
Wear face shield or tightly fitting safety goggles (chemical goggles) if splashing hazard exists.

Body protection:
Body protection must be chosen based on level of activity and exposure.

General safety and hygiene measures:
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

9. Physical and Chemical Properties

Form:	liquid	
Odour:	of vegetable oils	
Odour threshold:	No data available.	
Colour:	yellow to orange	
pH value:	5 - 7 (5 %(m), 20 °C)	(DGF-H-III)
freezing range:	No data available.	
decomposition point:	> 350 °C (1,013 hPa)	
Flash point:	> 250 °C The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.	(closed cup)
Flammability:	hardly combustible	
Lower explosion limit:	For liquids not relevant for classification and labelling.	
Upper explosion limit:	For liquids not relevant for classification and labelling.	
Autoignition:	> 300 °C Literature data.	
Vapour pressure:	8 hPa (20 °C)	
Density:	0.92 - 0.95 g/cm3 (20 °C)	
Vapour density:	not applicable	
Partitioning coefficient n-octanol/water (log Pow):	not applicable for mixtures	
Thermal decomposition:	> 350 °C	
Viscosity, dynamic:	No data available.	

Solubility in water:	immiscible
Solubility (qualitative):	miscible in all proportions solvent(s): oils,
Evaporation rate:	not applicable

10. Stability and Reactivity

Reactivity
No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals:
No corrosive effect on metal.

Oxidizing properties:
Based on its structural properties the product is not classified as oxidizing.

Formation of flammable gases:	Remarks:	Forms no flammable gases in the presence of water.

Chemical stability
The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions
May react with oxidizing agents.

Conditions to avoid
See MSDS section 7 - Handling and storage.

Incompatible materials
radical formers, oxidizing agents

Hazardous decomposition products

Decomposition products:
Possible thermal decomposition products: 2-propenal, carbon monoxide, carbon dioxide

Thermal decomposition:
> 350 °C

11. Toxicological information

Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity
Assessment of acute toxicity: Virtually nontoxic after a single ingestion.

Oral
Type of value: ATE
Value: > 5,000 mg/kg

Irritation / corrosion
Assessment of irritating effects: Prolonged exposure to the product can result in irritation of the skin and mucous membranes.

Sensitization
Assessment of sensitization: Based on available Data, the classification criteria are not met.

Chronic Toxicity/Effects

Repeated dose toxicity
Assessment of repeated dose toxicity: The information available on the product provides no indication of toxicity on target organs after repeated exposure.

Genetic toxicity
Assessment of mutagenicity: The chemical structure does not suggest a specific alert for such an effect.

Carcinogenicity
Assessment of carcinogenicity: Based on available Data, the classification criteria are not met.

Reproductive toxicity
Assessment of reproduction toxicity: The chemical structure does not suggest a specific alert for such an effect.

Other Information
The product has not been tested. The statements on toxicology have been derived from the properties of the individual components.

Symptoms of Exposure

No significant reaction of the human body to the product known.

12. Ecological Information

Toxicity

Aquatic toxicity
Assessment of aquatic toxicity:
There is a high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish

Information on: Docosahexaenoic acid
LC50 (96 h) > 100 mg/l, Brachydanio rerio (OECD Guideline 203, static)
The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates

Information on: Docosahexaenoic acid
EC50 (48 h) > 100 mg/l, Daphnia magna (OECD Guideline 202, part 1, static)
The details of the toxic effect relate to the nominal concentration. The product has low solubility in the test medium. An eluate has been tested.

Aquatic plants

Information on: Docosahexaenoic acid
EC50 (72 h) > 100 mg/l (growth rate), Desmodesmus subspicatus (OECD Guideline 201, static)
The details of the toxic effect relate to the nominal concentration. The product has low solubility in the test medium. An eluate has been tested.

Persistence and degradability

Assessment biodegradation and elimination (H2O)
Not readily biodegradable (by OECD criteria). Biodegradable.

Elimination information

Information on: Docosahexaenoic acid
60 - 70 % BOD of the ThOD (28 d) (OECD Guideline 301 F) (aerobic, activated sludge, domestic)
The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Bioaccumulative potential

Assessment bioaccumulation potential

Information on: Docosahexaenoic acid

Significant accumulation in organisms is not to be expected.
The product has not been tested. The statement has been derived from the properties of the individual components.

Mobility in soil

Assessment transport between environmental compartments

Information on: Docosahexaenoic acid

The substance will rapidly evaporate into the atmosphere from the water surface.
Adsorption to solid soil phase is expected.

Additional information

Other ecotoxicological advice:
The product has not been tested. The statements on ecotoxicology have been derived from the properties of the individual components.

13. Disposal considerations

Waste disposal of substance:
Observe national and local legal requirements.

Container disposal:
Uncontaminated packaging can be re-used. Packs that cannot be cleaned should be disposed of in the same manner as the contents.

14. Transport Information

Land transport
USDOT

Not classified as a dangerous good under transport regulations

Sea transport
IMDG

Not classified as a dangerous good under transport regulations

Air transport
IATA/ICAO

Not classified as a dangerous good under transport regulations

15. Regulatory Information

Federal Regulations

Registration status:

Chemical	TSCA, US	blocked / not listed
Food	TSCA, US	released / exempt

EPCRA 311/312 (Hazard categories): Refer to SDS section 2 for GHS hazard classes applicable for this product.

NFPA Hazard codes:
Health: 1 Fire: 1 Reactivity: 0 Special:

HMIS III rating
Health: 1 Flammability: 1 Physical hazard: 0

16. Other Information

SDS Prepared by:
BASF NA Product Regulations
SDS Prepared on: 2018/04/03

We support worldwide Responsible Care® initiatives. We value the health and safety of our employees, customers, suppliers and neighbors, and the protection of the environment. Our commitment to Responsible Care is integral to conducting our business and operating our facilities in a safe and environmentally responsible fashion, supporting our customers and suppliers in ensuring the safe and environmentally sound handling of our products, and minimizing the impact of our operations on society and the environment during production, storage, transport, use and disposal of our products.

IMPORTANT: WHILE THE DESCRIPTIONS, DESIGNS, DATA AND INFORMATION CONTAINED HEREIN ARE PRESENTED IN GOOD FAITH AND BELIEVED TO BE ACCURATE , IT IS PROVIDED FOR YOUR GUIDANCE ONLY. BECAUSE MANY FACTORS MAY AFFECT PROCESSING OR APPLICATION/USE, WE RECOMMEND THAT YOU MAKE TESTS TO DETERMINE THE SUITABILITY OF A PRODUCT FOR YOUR PARTICULAR PURPOSE PRIOR TO USE. NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE MADE REGARDING PRODUCTS DESCRIBED OR DESIGNS, DATA OR INFORMATION SET FORTH, OR THAT THE PRODUCTS, DESIGNS, DATA OR INFORMATION MAY BE USED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS. IN NO CASE SHALL THE DESCRIPTIONS, INFORMATION, DATA OR DESIGNS PROVIDED BE CONSIDERED A PART OF OUR TERMS AND CONDITIONS OF SALE. FURTHER, YOU EXPRESSLY UNDERSTAND AND AGREE THAT THE DESCRIPTIONS, DESIGNS, DATA, AND INFORMATION FURNISHED BY OUR COMPANY HEREUNDER ARE GIVEN GRATIS AND WE ASSUME NO OBLIGATION OR LIABILITY FOR THE DESCRIPTION, DESIGNS, DATA AND INFORMATION GIVEN OR RESULTS OBTAINED, ALL SUCH BEING GIVEN AND ACCEPTED AT YOUR RISK.
END OF DATA SHEET

We create chemistry

Safety Data Sheet
Dry n-3® DHA 11A

1. Identification

Product identifier used on the label

Dry n-3® DHA 11A

Recommended use of the chemical and restriction on use

Recommended use*: food additive(s)

* The “Recommended use” identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

Company:
BASF CORPORATION
100 Park Avenue
Florham Park, NJ 07932, USA

Telephone: +1 973 245-6000

Emergency telephone number

CHEMTREC: 1-800-424-9300
BASF HOTLINE: 1-800-832-HELP (4357)

Other means of identification

Synonyms: Docosahexaenoic acid

2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Classification of the product

Combustible Dust Combustible Dust (1) Combustible Dust

Label elements

Signal Word:
Warning

Hazard Statement:

May form combustible dust concentration in air.

Hazards not otherwise classified

The product is under certain conditions capable of dust explosion. The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. If applicable information is provided in this section on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture.

3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

CAS Number	Weight %	Chemical name
9005-25-8	20.0 - 24.0%	starch
6217-54-5	28.0 - 32.0%	Docosahexaenoic acid

4. First-Aid Measures

Description of first aid measures

General advice:
Remove contaminated clothing.

If inhaled:
Keep patient calm, remove to fresh air.

If on skin:
Wash thoroughly with soap and water.

If in eyes:
Wash affected eyes for at least 15 minutes under running water with eyelids held open.

If swallowed:
Rinse mouth and then drink plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms: No significant symptoms are expected due to the non-classification of the product.

Indication of any immediate medical attention and special treatment needed

Note to physician
Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media:
water spray, foam, dry powder, carbon dioxide

Unsuitable extinguishing media for safety reasons:
water jet

Additional information:
Avoid whirling up the material/product because of the danger of dust explosion.

Special hazards arising from the substance or mixture
Hazards during fire-fighting:
2-propenal, harmful vapours, carbon oxides
The substances/groups of substances mentioned can be released in case of fire. Burning produces harmful and toxic fumes. Dust explosion hazard. Self heating possible in the presence of air.

Advice for fire-fighters
Protective equipment for fire-fighting:
Wear a self-contained breathing apparatus.

Further information:
Dusty conditions may ignite explosively in the presence of an ignition source causing flash fire.

6. Accidental release measures

Further accidental release measures:
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Avoid the formation and build-up of dust - danger of dust explosion. Dust in sufficient concentration can result in an explosive mixture in air. Handle to minimize dusting and eliminate open flame and other sources of ignition.

Personal precautions, protective equipment and emergency procedures
Use personal protective clothing. Information regarding personal protective measures see, section 8.
Avoid dust formation.

Environmental precautions
Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up
For small amounts: Pick up with suitable appliance and dispose of.
For large amounts: Contain with dust binding material and dispose of.
Dispose of absorbed material in accordance with regulations. Avoid raising dust.

Nonsparking tools should be used.

7. Handling and Storage

Precautions for safe handling
Avoid dust formation. Provide exhaust ventilation if dust is formed.

Protection against fire and explosion:
Avoid dust formation. Dust in sufficient concentration can result in an explosive mixture in air. Handle to minimize dusting and eliminate open flame and other sources of ignition. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static

electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids (2013 Edition) for safe handling.

Conditions for safe storage, including any incompatibilities

Segregate from pesticides and fertilizers. Keep away from water.

Suitable materials for containers: Aluminium, Low density polyethylene (LDPE)

8. Exposure Controls/Personal Protection

Components with occupational exposure limits

starch	OSHA PEL	PEL 5 mg/m3 Respirable fraction ; PEL 15 mg/m3 Total dust ; TWA value 5 mg/m3 Respirable fraction ; TWA value 15 mg/m3 Total dust ;
	ACGIH TLV	TWA value 10 mg/m3 ;

Advice on system design:
It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection:
Wear a NIOSH-certified (or equivalent) respirator as necessary.

Hand protection:
Wear chemical resistant protective gloves.

Eye protection:
Wear safety goggles (chemical goggles) if there is potential for airborne dust exposures.

Body protection:
Body protection must be chosen based on level of activity and exposure.

General safety and hygiene measures:
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

9. Physical and Chemical Properties

Form:	powder
Odour:	faint odour
Odour threshold:	not determined
Colour:	white to light beige
pH value:	not determined

Melting point:	The substance / product decomposes therefore not determined.	
Boiling point:	The substance / product decomposes therefore not determined.	
Flash point:	not applicable, the product is a solid	
Flammability:	not highly flammable	(Regulation 440/2008/EC, A.10)
Lower explosion limit:	For solids not relevant for classification and labelling.	
Upper explosion limit:	For solids not relevant for classification and labelling.	
SADT:	> 75 °C Heat accumulation / Dewar 500 ml (SADT, UN-Test H.4, 28.4.4)	
Vapour pressure:	negligible	
Bulk density:	400 - 600 kg/m3	
Vapour density:	negligible	
Partitioning coefficient n-octanol/water (log Pow):	not applicable for mixtures	
Thermal decomposition:	>= 125 °C (DSC (DIN 51007)) Not a substance liable to self-decomposition according to UN transport regulations, class 4.1.	
Viscosity, dynamic:	not applicable, the product is a solid	
Solubility in water:	dispersible	
Evaporation rate:	negligible	

10. Stability and Reactivity

Reactivity
No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals:
No corrosive effect on metal.

Oxidizing properties:
not determined

Minimum ignition energy:
> 1 - < 4 J, 1,013 hPa, 20 °C, Inductivity: 1 mH (VDI 2263, sheet 1, 2.5)
The product is capable of dust explosion.

Chemical stability
The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions
Dust explosion hazard. Self heating possible in the presence of air.

Conditions to avoid
Avoid dust formation. Avoid all sources of ignition: heat, sparks, open flame. Avoid electro-static charge. Avoid heat.

Incompatible materials
radical formers, oxidizing agents

Hazardous decomposition products

Decomposition products:
Hazardous decomposition products: No hazardous decomposition products if stored and handled as prescribed/indicated.

Thermal decomposition:
>= 125 °C (DSC (DIN 51007))
Not a substance liable to self-decomposition according to UN transport regulations, class 4.1.

11. Toxicological information

Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity
Assessment of acute toxicity: Virtually nontoxic after a single ingestion.

Oral
Type of value: ATE
Value: > 5,000 mg/kg

Assessment other acute effects
Based on available Data, the classification criteria are not met.

Irritation / corrosion
Assessment of irritating effects: Not irritating to eyes and skin.

Information on: Docosahexaenoic acid
Assessment of irritating effects: Prolonged exposure to the product can result in irritation of the skin and mucous membranes. The product has not been tested. The statement has been derived from the structure of the product.

Sensitization
Assessment of sensitization: Based on available Data, the classification criteria are not met.

Information on: Caseins, potassium complexes

Aspiration Hazard
No aspiration hazard expected.

Chronic Toxicity/Effects

Repeated dose toxicity
Assessment of repeated dose toxicity: Based on available Data, the classification criteria are not met.

Information on: Docosahexaenoic acid
Assessment of repeated dose toxicity: Repeated oral uptake of the substance did not cause substance-related effects.

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Genetic toxicity
Assessment of mutagenicity: Based on the ingredients, there is no suspicion of a mutagenic effect.

Information on: Docosahexaenoic acid
Assessment of mutagenicity: Mutagenicity tests revealed no genotoxic potential.
The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Carcinogenicity
Assessment of carcinogenicity: Based on available Data, the classification criteria are not met.

Reproductive toxicity
Assessment of reproduction toxicity: Based on the ingredients, there is no suspicion of a toxic effect on reproduction.

Information on: Docosahexaenoic acid
Assessment of reproduction toxicity: The results of animal studies gave no indication of a fertility impairing effect.
The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Other Information
The product has not been tested. The statements on toxicology have been derived from the properties of the individual components.

Symptoms of Exposure

No significant symptoms are expected due to the non-classification of the product.

12. Ecological Information

Toxicity

Aquatic toxicity
Assessment of aquatic toxicity:
There is a high probability that the product is not acutely harmful to aquatic organisms. At the present state of knowledge, no negative ecological effects are expected.

Aquatic toxicity

Information on: Docosahexaenoic acid
Assessment of aquatic toxicity:
There is a high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Persistence and degradability

Assessment biodegradation and elimination (H2O)
Not readily biodegradable (by OECD criteria). The product has not been tested. The statement has been derived from the properties of the individual components.

Assessment biodegradation and elimination (H2O)

Information on: Docosahexaenoic acid

Not readily biodegradable (by OECD criteria). Biodegradable.

Elimination information

Information on: Docosahexaenoic acid
60 - 70 % BOD of the ThOD (28 d) (OECD Guideline 301 F) (aerobic, activated sludge, domestic)
The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Bioaccumulative potential

Assessment bioaccumulation potential
The product has not been tested. The statement has been derived from the properties of the hydrolysis products.

Assessment bioaccumulation potential

Information on: Docosahexaenoic acid

Significant accumulation in organisms is not to be expected.
The product has not been tested. The statement has been derived from the properties of the individual components.

Mobility in soil

Assessment transport between environmental compartments
The product has not been tested. The statement has been derived from the properties of the individual components.

Information on: Docosahexaenoic acid

The substance will rapidly evaporate into the atmosphere from the water surface.
Adsorption to solid soil phase is expected.

Additional information

Other ecotoxicological advice:
The product has not been tested. The statements on ecotoxicology have been derived from the properties of the individual components.

13. Disposal considerations

Waste disposal of substance:
Observe national and local legal requirements.

Container disposal:
Dispose of in accordance with national, state and local regulations.

14. Transport Information

Land transport
USDOT

Hazard class:	4.2
Packing group:	III
ID number:	UN 3088
Hazard label:	4.2
Proper shipping name:	SELF-HEATING SOLID, ORGANIC, N.O.S. (contains DOCOSAHEXAENOIC ACID)

Sea transport
IMDG

Hazard class:	4.2
Packing group:	III
ID number:	UN 3088
Hazard label:	4.2
Marine pollutant:	NO
Proper shipping name:	SELF-HEATING SOLID, ORGANIC, N.O.S. (contains DOCOSAHEXAENOIC ACID)

Air transport
IATA/ICAO

Hazard class:	4.2
Packing group:	III
ID number:	UN 3088
Hazard label:	4.2
Proper shipping name:	SELF-HEATING SOLID, ORGANIC, N.O.S. (contains DOCOSAHEXAENOIC ACID)

15. Regulatory Information

Federal Regulations

Registration status:

Chemical	TSCA, US	blocked / not listed
Food	TSCA, US	released / exempt

EPCRA 311/312 (Hazard categories): Refer to SDS section 2 for GHS hazard classes applicable for this product.

State regulations

State RTK	CAS Number	Chemical name
PA	9005-25-8	starch

NFPA Hazard codes:

Health: 1 Fire: 1 Reactivity: 0 Special:

HMIS III rating
Health: 1 Flammability: 1 Physical hazard: 0

16. Other Information

SDS Prepared by:
BASF NA Product Regulations
SDS Prepared on: 2018/10/10

We support worldwide Responsible Care® initiatives. We value the health and safety of our employees, customers, suppliers and neighbors, and the protection of the environment. Our commitment to Responsible Care is integral to conducting our business and operating our facilities in a safe and environmentally responsible fashion, supporting our customers and suppliers in ensuring the safe and environmentally sound handling of our products, and minimizing the impact of our operations on society and the environment during production, storage, transport, use and disposal of our products.

END OF DATA SHEET

GOED OMEGA-3

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3

Codex Code of Practice on the Mitigation of 3-MCPD and Glycidyl-esters in Refined Oils Approved

May 6, 2019: The Codex Code of Practice (CoP) entitled "Reduction of 3-Monochloropropane-1,2-diol esters (3-MCPDE) and glycidyl esters (GE) in Refined Oils and Food Products Made with Refined Oils" was approved during the 13th Meeting of the Codex Committee on Contaminants in Foods (CCCF13), held last week in Yogyakarta, Indonesia (April 29 - May 3rd, 2019). The document is expected to be officially adopted by the Codex Alimentarius Commission in July 2019.

GOED contributed to the development of this CoP through its participation in an Electronic Working Group (EWG) during the past two years. Initially this CoP was being developed for the mitigation of 3-MCPDE and GE in refined vegetable oils, notably to reduce the levels of these process contaminants in refined palm oil. GOED pointed out during last year's CCCF meeting that process contaminant mitigation is also of relevance to fish oils, since these contaminants can also be formed during the production of refined fish oils. GOED and several country delegations supported the proposal that the CoP should therefore also encompass any refined edible oils in addition to vegetable oils.

In order to substantiate the broader scope of the CoP, GOED provided significant information to the EWG on reduction measures that are used at industrial scale by GOED members. With the approval of the CoP, Codex has recognized the importance to inform governments about suitable mitigation approaches for these process contaminants in any refined oil used as food. The CoP also serves as a useful guide for fish oil-producing companies in GOED that need information on how to reduce the levels of 3-MCPDE and GE in their refined oils. The CoP also provides a basis for potential future work by Codex in which maximum limits may be set for these contaminants in refined edible oils. Such work is ongoing in Europe (reported last on by GOED on February 18th, 2019.

Mitigation approaches provided in the CoP need to be tested to identify the most successful ones for companies' products. Only mitigation approaches that are known to have been implemented at industrial scale for specific types of oils are listed. Reduction measures listed as suitable for vegetable oils may also be considered instructive to produce refined fish oils with low levels of 3-MCPDE and GE. From the information provided by members over the past year, GOED has observed that the implementation of a combination of mitigation approaches is particularly effective in lowering the levels of process contaminants in refined oils.

GOED would like to thank all members who generously provided information on their production technologies, which allowed GOED to strengthen the CoP, ultimately leading to the current approval.

GOED last reported on this Codex Code of Practice on March 11, 2019, January 14, 2019, January 2nd, 2019, and November 26th, 2018.

Any questions can be directed to Gerard Bannenberg.

1075 Hollywood Avenue, Salt Lake City, UT 84105 | +1 801-746-1413

APPENDIX IV

DRAFT CODE OF PRACTICE FOR THE REDUCTION OF 3-MONOCHLOROPROPANE-1,2- DIOL ESTERS (3-MCPDE) AND GLYCIDYL ESTERS (GE) IN REFINED OILS AND FOOD PRODUCTS MADE WITH REFINED OILS

(AT STEP 8)

INTRODUCTION

1. Edible oils, which include vegetable oils and fish oils, are produced from various commodities, including fruits, seeds, nuts, and fish. Refining of edible oils (at temperatures of about 200°C or higher) can produce 3-monochloropropane-1,2-diol (MCPD) esters (3-MCPDE) and glycidyl esters (GE).
2. Exposure to 3-MCPDE and GE can occur through consumption of refined oils and various food products containing refined oils, for example, infant formula, dietary supplements, fried potato products, and fine bakery wares.
3. Toxicology studies show that 3-MCPDE and 3-MCPD have effects on the kidney and male reproductive organs, and are non-genotoxic carcinogens. GE and glycidol are genotoxic carcinogens.[1]
4. The 83rd JECFA session evaluated 3-MCPD, 3-MCPDE, GE and glycol and recommended that efforts to reduce 3-MCPDE and 3-MCPD in infant formula be implemented and that measures to reduce GE and glycidol in fats and oils continue, particularly when used in infant formula.
5. Different types of unrefined oils have different capacities to form 3-MCPDE and GE during deodorization (part of the refining process).
6. Processing conditions during refining have an important effect on formation of 3-MCPDE and GE for all oil types. Most unrefined oils do not contain detectable levels of 3-MCPDE or GE.
7. For vegetable oils, factors that contribute to capacity to form 3-MCPDE and GE during refining include climate, soil and growth conditions of source plants or trees, their genotype, and harvesting techniques. These factors all affect the levels of precursors of 3-MCPDE and GE (e.g. acylglycerols, chlorine-containing compounds).
8. 3-MCPDE forms primarily from the reaction between chlorine containing-compounds and acylglycerols like triacylglycerols (TAGs), diacylglycerols (DAGs), and monoacylglycerols (MAGs). GE forms primarily from DAGs or MAGs.
9. Some chlorinated compounds are precursors for 3-MCPDE formation. Oil producing plants or trees absorb chloride ions (in the form of chlorinated compounds) during plant or tree growth from soil (including from fertilizers and pesticides) and from water, and these chloride ions are converted into reactive chlorinated compounds, leading to formation of 3-MCPDE during oil refining.
10. Oil fruits and seeds contain the enzyme lipase; lipase activity increases with fruit maturation, while the lipase activity in seeds remains stable. Lipase interacts with oil from mature fruits to rapidly degrade TAGs into free fatty acids (FFAs), DAGs, and MAGs, while the effect of lipase in seeds that are appropriately stored is negligible.
11. GE formation begins at about 200°C. GE formation increases exponentially with increasing temperature. When DAGs exceed 3-4% of total lipids, the potential for GE formation increases. Formation of 3-MCPDE occurs at temperatures as low as 160-200°C, and formation does not increase with higher temperatures.

[1] 3-MCPDE and GE, following consumption, are broken down in the body to 3-MCPD and glycidol, respectively.

12. Because 3-MCPDE and GE are formed via different mechanisms, different mitigation strategies are needed to control their formation. Due to the different formation mechanisms, there generally is no relationship between relative levels of 3-MCPDE and GE in individual oil samples.

13. GE is generally easier to mitigate than 3-MCPDE, because its formation is directly associated with elevated temperatures (with formation beginning at about 200°C and becoming more significant at temperatures >230°C). GE is formed primarily from DAGs and does not require the presence of chlorinated compounds. Oils can be deodorized at temperatures below 230°C to avoid significant GE formation. However, it is not practical to decrease deodorization temperatures below the threshold that would lead to 3-MCPDE formation (160-200°C), as that could affect the quality and safety of the oil.

14. Although 3-MCPDE and GE are primarily produced during deodorization, mitigation measures can be applied across the edible oil production chain, from agricultural practices for vegetable oils (e.g. cultivation, harvesting, transporting, and storing of fruits and seeds), to oil milling and refining (e.g. crude oil production and treatment, degumming/bleaching, and deodorization), as well as to post-refining measures (e.g. additional bleaching and deodorization and use of activated bleaching earth). Where possible, it may be best to remove precursors at the earlier stages of processing, to minimize the formation of 3-MCPDE and GE.

15. There are a wide range of methods to mitigate 3-MCPDE and GE, and the applicable methods used will vary depending on different conditions (including the oil source, the refining process, and the type of equipment in use). In addition, multiple methods may need to be combined to reduce 3-MCPDE and GE in oils. Manufacturers should select and apply those techniques that are appropriate to their own processes and products.

16. In concert with mitigation of 3-MCPDE and GE, it is important to also consider the overall impacts on the quality of refined oils and oil-based products, including product properties such as smell and taste, FFA profiles, stability attributes, levels of nutrients, and removal of contaminants such as pesticides and mycotoxins. In addition, environmental impacts of the recommended mitigation practices should be considered.

17. Although most work on mitigation of 3-MCPDE and GE in refined oils has focused on palm oil, some of the information and experience on mitigation of 3-MCPDE and GE in palm oil may be applicable to mitigation of 3-MCPDE and GE in other refined oils. Therefore, where data are available, this document specifies when the mitigation approach is specific to palm oil, and when it may be more widely applicable to other refined oils, including fish oils.

SCOPE

18. This Code of Practice intends to provide national and local authorities, producers, manufacturers, and other relevant bodies with guidance to prevent and reduce formation of 3-MCPDE and GE in refined oils and food products made with refined oils. This guidance covers three strategies (where information is available) for reducing 3-MCPDE and GE formation:

    (i) Good agricultural practices,

    (ii) Good manufacturing practices, and

    (iii) Selection and uses of refined oils in food products made from these oils.

RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP) AND GOOD MANUFACTURING PRACTICES (GMP)

19. Producing edible vegetable oils involves several major steps: cultivating, harvesting, transporting, and storing the fruits and seeds for further processing; palm oil milling where fruit is sterilized and crude oil is extracted; oilseed crushing where oilseeds are cleaned, ground, and steamed and crude oil is extracted; and refining of the crude oils.

20. Producing edible fish oils involves several major steps: harvesting the fish, steam cooking, de-watering/wet reduction (which involves pressing the liquor, separating the oil and water, and optionally, water washing the oil), and refining of the crude oils.

21. Refining edible oils consists of two main types; chemical or physical refining. Chemical refining consists of degumming (removal of phospholipids); neutralization (addition of hydroxide solution to remove FFAs through formation of soaps); bleaching (using clays) to reduce colors and remove remaining soaps and gums, trace metals, and degradation products; and deodorization (i.e. a steam-distillation process carried out at low pressures, 1.5-6.0 mbar, and elevated temperatures, 180 - 270°C) to remove FFA, colours, and volatile compounds, including certain contaminants. Physical refining involves degumming, bleaching, and deodorization (which occurs at higher temperatures than chemical refining), as it does not have a neutralization step. While several factors influence the selection of physical refining, it is typically conducted on oils containing low levels of phospholipids.

AGRICULTURAL PRACTICES FOR VEGETABLE OILS

22. When planting new trees, farmers should consider selecting oil palm plant varieties with low lipase activity in oil fruits, if available, as low lipase activity is one factor that can reduce formation of FFAs and acylglycerol precursors.

23. During cultivation of oil plants or trees, farmers should minimize use of substances such as fertilizers, pesticides, and water that have excessive amounts of chlorine-containing compounds, in order to reduce chlorine uptake by the fruits and seeds. Non-chlorinated sulfate fertilizers could serve as an alternative to chlorine-containing fertilizers.

24. Farmers should harvest oil palm fruits when they are at optimal ripeness, minimize handling of the fruits to reduce bruising and prevent formation of FFAs, and avoid using damaged or overripe fruits, which may be associated with higher 3-MCPDE and GE formation.

25. Farmers should transport oil palm fruits to oil mills as soon as possible.

OIL MILLING AND REFINING

Crude Oil Production and Treatment

26. Processors should consider storing oil seeds for milling at cool temperatures (e.g. < 25°C) and dry conditions (optimally <7% moisture content) to help ensure low levels of lipase.

27. Following receipt of oil palm fruits at the mill, processors should sterilize the fruits immediately (preferably within less than 2 days of harvesting) at temperatures at or below 140°C to inactivate lipases (with temperatures varying depending on the sterilization method). (Fruits may be washed prior to sterilization to remove chlorine precursors.) For oilseeds, processors should clean, grind, and heat to inactivate lipases.

28. Processors should consider washing crude vegetable oil with chlorine-free water to remove chlorine-containing compounds.

29. Processors should avoid using residual vegetable oil recovered from solvents or additional extractions, as this oil tends to have higher levels of precursors (e.g. DAGs, chlorine-containing compounds).

30. Processors should assess precursors in batches of crude vegetable oils or fish oils (e.g. DAGs, FFAs, chlorine-containing compounds) to adjust refining parameters and target appropriate mitigation strategies depending on the type of vegetable oil or fish oil being processed and processing conditions.

31. Preferentially refining crude vegetable oil or fish oil with low concentrations of precursors can produce finished oils with lower levels of 3-MCPDE and GE.

Degumming

32. Processors should use milder and less acidic conditions (e.g. either degumming with a low concentration of phosphoric, citric, or other acids or water degumming) to decrease 3-MCPDE in vegetable oils or fish oils. The concentration of acid needed depends on the quality of the crude vegetable oil or fish oil. Care should be taken to remove sufficient concentrations of phospholipids and acid to ensure quality.

33. Lowering the degumming temperature may help to reduce formation of 3-MCPDE precursors in vegetable oils; however, the degumming temperature will depend on numerous factors including the type of vegetable oil.

Neutralization

34. Using chemical refining (i.e., neutralization) as an alternative to physical refining can help remove precursors (e.g. chloride) and reduce FFAs, which may allow for lower deodorization temperatures in vegetable oils or fish oils. However, chemical refining can lead to excessive oil loss (especially for palm oil due to higher FFA levels) and may have a greater environmental impact than physical refining.

Bleaching

35. Use of greater amounts of bleaching clay may reduce formation of 3-MCPDE and GE in all vegetable oils and fish oils. However, bleaching clays that contain significant amounts of chlorine-containing compounds should be avoided.

36. Use of more pH-neutral clays reduces the acidity and potential to form 3-MCPDE in palm oil, some seed oils, and fish oil.

Deodorization

37. Processors should consider conducting deodorization of vegetable oils and fish oils at reduced temperatures to decrease formation of GE. For example, it has been suggested to conduct deodorization at 190-230°C for vegetable oils and less than 190°C for fish oils. The temperature will vary depending on the residence time of oil. Processors can determine the optimal conditions for their processes.

38. As an alternative to traditional deodorization, processors can conduct dual deodorization of vegetable oils and fish oils (2-stage deodorization) to reduce thermal load in oil and to decrease formation of GE, with a smaller reduction in 3-MCPDE. This includes both a shorter deodorization period at a higher temperature and a longer deodorization period at a lower temperature. Consideration needs to be given to parameters such as temperature, vacuum pressure, and time, and variations in equipment design and capability. Also, additional post processing may be required to reduce levels of GE.

39. Use of a stronger vacuum facilitates evaporation of volatile compounds due to the increased steam volume and rate of stripping, contributing to decreased deodorization temperatures and reduced formation of GE, and to a lesser extent 3-MCPDE, in vegetable and fish oils.

40. Short-path distillation[2] (in place of deodorization) has been shown to reduce the thermal load and formation of esters in fish oil, contributing to lower amounts of 3-MCPDE and GE in comparison to conventional deodorization. However, additional post processing using mild deodorization is needed to address sensory considerations.

TREATMENT POST REFINING

41. The following recommended practices can be used for reducing levels of 3-MCPDE and GE in refined oils. These practices may be most appropriate for oils with 3-MCPDE and GE levels that are higher than desired for their intended use.

42. Additional bleaching and deodorization following initial bleaching and deodorization has been shown to achieve lower levels of GE in refined palm oil. (The second deodorization should occur at a lower temperature than the first deodorization.)

43. Application of activated bleaching earth during post refining has been shown to reduce GE in refined vegetable oils.

44. Use of short-path distillation (pressure: <1 mbar and temperature: 120 to 270°C) on bleached and deodorized vegetable oil can reduce acylglycerol components and levels of 3-MCPDE and GE.

45. Treatment of refined MCT (medium-chain triacylglycerols) oil with fatty acids and a cation counterion, such as an alkaline metal, as well as one or more bases converts 3-MCPDE to MAGs, DAGs and TAGs, and GEs to DAGs.

[2] Short-path distillation enables gentle removal of volatile compounds at relatively low temperatures. This is accomplished through reduced pressure, where the boiling point of the compound to be separated is lowered and there is increased efficiency due to the short distance between the evaporator and the condenser surface.

SELECTION AND USES OF REFINED OILS IN FOOD PRODUCTS MADE FROM THESE OILS

Oil selection

46. Selecting refined vegetable oils and fish oils with low levels of 3-MCPDE and GE (e.g. either through natural occurrence or through application of mitigation measures) results in lower levels of 3-MCPDE and GE in finished products containing these oils. For example, variation in levels of 3-MCPDE and GE in infant formula has been observed, which may be due to the use of oils with different levels of 3-MCPDE and GE; therefore, selection of oils low in 3-MCPDE and GE can result in infant formulas with lower 3-MCPDE and GE levels. However, manufacturers also may have to consider quality or compositional factors. For example, for infant formula, refined oils are selected by manufacturers to ensure these products meet compositional criteria, e.g. national criteria or those established in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981).

Processing modifications

47. Reducing the amount of refined vegetable oils and fish oils used in finished products may be an alternative to reduce the levels of 3-MCPDE and GE in the finished product. However, this could impact the organoleptic or nutritional qualities of the finished products.

48. Use of refined vegetable oils themselves during frying does not contribute to formation of additional 3-MCPDE and GE, but rather the formation of additional 3-MCPDE during frying may result from the type of food that is fried (e.g., meat and fish products).

ANNEX I

POTENTIAL MITIGATION MEASURES FOR REDUCING 3-MCPDE AND GE
The mitigation measures are not listed in order of priority.
It is recommended that reduction measures be tested to identify the most successful for your own product.

Production Stage	Mitigation measures
AGRICULTURAL PRACTICES FOR VEGEGETABLE OILS	• Select oil palm plant varieties with low lipase activity, if available. • Minimize use of substances such as fertilizers, pesticides, and irrigation water that contain excessive amounts of chlorine-containing compounds during oil plant/tree cultivation. • Harvest oil palm fruits when they are at optimal ripeness. Minimize handling of the fruit. Avoid using damaged or overripe fruit. • Transport oil palm fruits to oil mills as soon as possible.
OIL MILLING AND REFINING	**Crude Oil Production and Treatment** • Store oil seeds at cool temperatures and dry conditions. • Sterilize oil palm fruit at temperatures at or below 140°C. Clean, dry, and heat oilseeds to inactivate lipases. • Wash crude vegetable oil with chlorine-free water. • Avoid using residual vegetable oil recovered from solvents or extractions. • Assess precursors (e.g. DAGs, FFAs, and chlorine compounds) in batches of crude vegetable oil or fish oil to adjust refining parameters. • Preferentially refine crude vegetable oil or fish oil with low concentrations of precursors.
	Degumming • Use milder and less acidic conditions (e.g. either degumming with a low concentration of acid or water degumming) in vegetable oils or fish oils. • Lower the degumming temperature in vegetable oils.
	Neutralization • Use chemical refining (i.e. neutralization) as an alternative to physical refining in vegetable oils or fish oils.
	Bleaching • Use greater amounts of bleaching clay in vegetable oils and fish oils. • Use more pH-neutral clays to reduce acidity in palm oils, some seed oils, and fish oils.

POTENTIAL MITIGATION MEASURES FOR REDUCING 3-MCPDE AND GE

The mitigation measures are not listed in order of priority.

It is recommended that reduction measures be tested to identify the most successful for your own product.

Production Stage	Mitigation measures
OIL MILLING AND REFINING	**Deodorization** • Conduct deodorization of vegetable oils or fish oils at reduced temperatures. The temperatures will vary depending on residence time of oil. • Conduct dual deodorization of vegetable oils and fish oils (2-stage deodorization) as an alternative to traditional deodorization. • Use a stronger vacuum to facilitate evaporation of volatile compounds and to contribute to decreased deodorization temperatures in vegetable oils and fish oils. • Use short-path distillation (in place of deodorization) to reduce the thermal load in fish oil.
TREATMENT POST REFINING	• Conduct additional bleaching and deodorization following initial bleaching and deodorization of refined palm oil. • Apply activated bleaching clay to refined vegetable oils. • Use short-path distillation on bleached and deodorized vegetable oils. • Treat refined MCT (medium-chain triglyceride) oil with bases, fatty acids, and alkaline metals to convert 3-MCPDE to MAGs, DAGs and TAGs and GE to DAGs.
SELECTION AND USES OF REFINED OILS	**OIL SELECTION** • Select refined vegetable oils or fish oils with lower levels of 3-MCPDE and GE. **PROCESS MODIFICATIONS** • Reduce the amount of refined vegetable oils or fish oils in finished products.

Compositional information

Version 1.1, 12.2016

DHA Algal Oil

PRD no. 30599327
Manufacturing site: BASF Personal Care and Nutrition GmbH, Illertissen, Germany

Composition:

Ingredients	Content (%)
Oil from the micro-algae	
Schizochytrium sp.	99
Tocopherol-rich extract E 306*	max. 1

* standardized with sunflower oil

Compositional information

Version 4.1, 05.2019

Dry n-3® DHA 11A

PRD no. 30602682
Manufacturing site: BASF A/S, Ballerup, Denmark

Composition*

Ingredients	Content (%)
DHA-rich algal oil:	
[Oil from the micro-algae *Schizochytrium* sp. (food grade),	min. 25
Tocopherol-rich extract (E306),	max. 1
Mono- and diglycerides of fatty acids (E471),	max. 0.1
Lecithins from soybean (E322),	max. 0.1
Ascorbyl palmitate (E304)]	max. 0.1
Glucose syrup (food grade)	20-40
Corn starch (maize starch, food grade)	15-30
Edible acid casein from milk (food grade)	7-15
(solubilized with processing aid potassium hydroxide)	
Sodium ascorbate (E301)	3-7
Water**	max. 5
Tricalcium phosphate (E341)	max. 2

*typical values **based on loss of drying

1. In question 6 of our second set of questions (October 18, 2019 questions), we requested additional information on levels of 3-monochloropropane-1,2-diol (3-MCPD) esters in your algal oil and the "mitigation processes" you indicated "are underway to reduce the formation of these process contaminants." In your response (October 31, 2019 amendment), you noted that "BASF follows the attached mitigation strategy of Codex specifically through the adjustment of the bleaching conditions." Based on this statement and the clarification (by phone, November 21, 2019) that there is no chemical refining step to neutralize and remove free fatty acids (and potentially remove precursors of 3-MCPD such as chloride), we request that you provide additional information about the bleaching step and if it has been modified since the submission of the analytical data for 3-MCPD provided in the original notice.

> Response: The bleaching step uses bentonites (silicates) which are dispersed in the hot oil under nitrogen together with activated carbon and filter aids. Those processing aids are subsequently removed by plate filtration. The mitigation for the reduction of 3-MCPD esters is based on a process optimization using the optimum quantities of bleaching earths (bentonites such as Trisyl and Tonsyl types) on oil. It is also based on the proper combination/ratio of the bleaching earths from approved suppliers. This optimization is a part of our continuous quality improvement strategy. The bleaching step is consistent since the submission.

2. FDA has reviewed both fish oils and DHA algal oils for use in accordance with the menhaden oil regulation (21 CFR 184.1472), but with modifications in use levels to account for the levels of DHA and EPA in fish and algal oils. Menhaden oil contains approximately 20% EPA+DHA. We have reviewed GRAS determinations for DHA oils produced by *Schizochytrium* sp. algae for uses in accordance with the menhaden oil regulation (e.g., GRNs 000137, 000732); however, since these algal oils have contained >20% DHA and little or no EPA, the intended uses of the DHA algal oils have been scaled to provide a targeted amount of DHA (1.5 g/p/d) in the diet. In question 12 of our October 18, 2019 questions regarding GRN 000862, we had previously noted the following: "Your cover letter indicates maximum use levels of 1.45% and 0.87% by weight DHA algal oil in meat and poultry respectively. Table 9 of your notice lists maximum use levels of 1.25% and 0.75% by weight DHA oil in meat and poultry products respectively. Please clarify the maximum intended use levels for DHA algal oil in food as served for meat and poultry." In your October 31, 2019 amendment, you responded that "the maximum intended use is that stated in the safe and suitable list" for meat and poultry products. However, we note that the levels cited for DHA algal oil in the FSIS list are based on oil containing 35% DHA (based on GRN 000137). We note that, given your statement responding to question 3 in your October 31, 2019 amendment that BASF no longer intends to reduce the DHA content of the oil to 35%, we would expect your use levels to reflect approximately ¼ those of menhaden oil levels and that the 1.25% level in meat and 0.75% level in poultry reflect the higher level of DHA (approximately 40%) in your algal oil. Please provide a statement that the use levels of BASF's algal oil and algal oil powder will be adjusted as necessary to provide no more than 1.5 g DHA per person per day for food categories listed in 21 CFR 184.1472 (menhaden oil).

> Response: The use levels of BASF's algal oil and algal oil powder will be adjusted as necessary to provide no more than 1.5 g DHA per person per day for food categories listed in 21 CRR 184.1472 (menhaden oil).

3. Please clarify that all liquid product intended for use in infant formula will enter a stream that goes through retort or pasteurization.

Response: All liquid product intended for use in infant formula goes through a pasteurization step.

4. References to "Enterobacteria" on pages 16, 150, 152, 154, 158 and 161 of the notice; in answers to question 2 and the provided stability data of the September 27, 2019 amendment; in the answer to question 11 of the October 31, 2019 amendment should read "*Enterobacteriaceae*". Please state whether you agree.

Response: We agree

5. Provide results from analyses of three non-consecutive batches of algal oil and of algal oil powder for *Enterobacteriaceae* in a sample size of 10 grams.

Response: Testing with third party labs initiated. Algal oil tests are already completed and reports are attached to this letter. Powder tests ongoing, results are expected before end of this year.

6. Please clarify whether the provided specifications for *Cronobacter sakazakii* in algal powder (pg. 16) are performed using a 300-gram sample. If so, please provide results from analyses of three non-consecutive batches for *C. sakazakii* in a sample size of 10 grams of algal oil powder.

Response: Testing with third party labs initiated. Algal oil tests are already completed and reports are attached to this letter. Powder tests ongoing, results are expected before end of this year.

7. There are the "internal limits" given in response to question 1b in your September 27, 2019 amendment that differ from the limits given in response to question 3e of the same amendment, where mercury and lead are given as ≤0.02 mg/kg each. Please clarify the limits for lead and mercury and correct any errors in these tables.

Response: The specifications for heavy metals in our response to question 3e on September 27 should read as follows: max lead, 0.1 mg/kg; mercury, max 0.02 mg/kg; arsenic, max 0.1 mg/kg.

Elemental Analysis						
	DH5750	**DH5751**	**DH5752**	**016888247**	**BASF Specs**	**FCC Specs**
Arsenic (ppm)	<0.1	<0.1	<0.1	<0.1	≤0.1	≤0.1
Lead (ppm)	<0.02	<0.02	<0.02	<0.05	≤0.1	≤0.1
Mercury (ppm)	<0.005	<0.005	<0.005	<0.005	≤0.02	≤0.1

8. For the record, please provide copies of the RSSL certificates of analysis that do not state "provisional- not approved" or provide a statement confirming that the final/approved values did not change from those submitted in your September 27, 2019 amendment.

Response: Attached are copies of the RSSL certificates of analysis without the statement "provisional-not approved".

Attachments

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Bad Bocklet 06 Dec 2019 / BM / Basfll

Certificate of Analysis

LS No:	191203-0127-001	**LS Code:**	1484417 / L
Product name:	DHA Algal Oil		
Lot No:	0016888247_1		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note
-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
This document was created by a GMP-supervised LIMS and approved by electronic signature.
Approved on 06 Dec 2019 at 15:32 by Alexander Klauer, Specialist Manager.

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USt.-Id.: DE 317 022 554
EORI-Nr.: DE 924 152 552 472 760

Ärztlicher Leiter:
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Hypo Vereinsbank Schweinfurt
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IBAN: DE08 7907 0016 0840 1325 00

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Dipl. Kfm. Werner Wohnhas
Geschäftsführende Direktoren:
Dr. Jürgen Bailes, Sabine Fingerhut-Heinemann

BIC: HYVEDEMM451
BIC: DEUTDEMM790

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Bad Bocklet 06 Dec 2019 / BM / Basfil

Certificate of Analysis

LS No:	191203-0127-002	**LS Code:**	1484418 / L
Product name:	DHA Algal Oil		
Lot No:	0016888247_2		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note
-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
This document was created by a GMP-supervised LIMS and approved by electronic signature.
Approved on 06 Dec 2019 at 15:33 by Alexander Klauer, Specialist Manager.

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EORI-Nr.: DE 924 152 552 472 760

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IBAN: DE08 7907 0016 0840 1325 00

Verwaltungsrat (Vors.):
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Geschäftsführende Direktoren:
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BIC: HYVEDEMM451
BIC: DEUTDEMM790

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Bad Bocklet 06 Dec 2019 / BM / BasfII

Certificate of Analysis

LS No:	191203-0127-003	**LS Code:**	1484419 / L
Product name:	DHA Algal Oil		
Lot No:	0016888247_3		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note
-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
This document was created by a GMP-supervised LIMS and approved by electronic signature.
Approved on 06 Dec 2019 at 15:40 by Alexander Klauer, Specialist Manager.

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EORI-Nr.: DE 924 152 552 472 760

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IBAN: DE10 7932 0075 0002 0110 00
IBAN: DE08 7907 0016 0840 1325 00

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Geschäftsführende Direktoren:
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Bad Bocklet 06 Dec 2019 / BM / BasfIl

Certificate of Analysis

LS No:	191203-0127-004	**LS Code:**	1484420 / L
Product name:	DHA Algal Oil		
Lot No:	0019208801_1		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note
-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
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Approved on 06 Dec 2019 at 15:41 by Alexander Klauer, Specialist Manager.

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Bad Bocklet 06 Dec 2019 / BM / BasfII

Certificate of Analysis

LS No:	191203-0127-005	**LS Code:**	1484422 / L
Product name:	DHA Algal Oil		
Lot No:	0019208801_2		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note
-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
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Approved on 06 Dec 2019 at 15:43 by Alexander Klauer, Specialist Manager.

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Certificate of Analysis

LS No:	191203-0127-006	**LS Code:**	1484423 / L
Product name:	DHA Algal Oil		
Lot No:	0019208801_3		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note
-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
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Approved on 06 Dec 2019 at 15:43 by Alexander Klauer, Specialist Manager.

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Bad Bocklet 06 Dec 2019 / BM / BasfII

Certificate of Analysis

LS No:	191203-0127-007	**LS Code:**	1484424 / L
Product name:	DHA Algal Oil		
Lot No:	0020536261_1		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note

-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
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Bad Bocklet 06 Dec 2019 / BM / BasfII

Certificate of Analysis

LS No:	191203-0127-008	**LS Code:**	1484425 / L
Product name:	DHA Algal Oil		
Lot No:	0020536261_2		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note
-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
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Certificate of Analysis

LS No:	191203-0127-009	**LS Code:**	1484426 / L
Product name:	DHA Algal Oil		
Lot No:	0020536261_3		
Entry temperature:	room temperature		
Your Order No:	4944273100		
Order dated:	29 Nov 2019	**Sample receipt:**	03 Dec 2019
Start of test:	04 Dec 2019	**End of test:**	06 Dec 2019

according to paragraph 64 LFGB*

Parameter	Method	Specification / Demands	Result
Cronobacter sakazakii, qualitative	SOP 9.040		not detected / 10 g
Enterobacteriaceae, qualitative	*L 00.00-133/1, mod.		not detected / 10 g
			All results confirm with the specifications of the order

Note
-L 00.00-133/1, mod. corresponds ISO 21528-2, mod.
-SOP 9.040, corresponds ISO 22964, mod.

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
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Germany

Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-1** Your Refs: 96914 DH 5750
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C12:0	0.8	%
	C13:0(I)	0.1	%
	C14:0	9.1	%
	C14:1	0.1	%
	C15:0	0.4	%
	C16:0	20.8	%
	C16:1	4.1	%
	C17:0	0.1	%
	C18:0	0.7	%
	C18:1(trans)	0.1	%
	C18:1(cis)	7.0	%
	C18:2(cis)	0.5	%
	C18:3(alpha)	0.2	%
	C20:0	0.1	%
	C20:1	0.4	%
	C22:1	0.5	%
	C24:0	0.1	%
	C20:3 (n6)	0.1	%
	C20:4 (n6)	0.3	%
	C20:5 (n3)	1.6	%
	C22:6 (n3)	44.5	%
	C22:5 (n6)	8.1	%
	C22:5 (n3)	0.3	%

Normalised fatty acid profile (%).

Science With Service

Approved By:
Aurelia Laluc
Senior Scientist I
(Investigative Analysis)

24 April 2018

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-1** Your Refs: 96914 DH 5750
Description: DHA Algal Oil

Method	Analysis	Result	Units
TM-331	alpha tocopherol	550	mg/kg
TM-331	beta tocopherol	92	mg/kg
TM-331	gamma tocopherol	1544	mg/kg
TM-331	delta tocopherol	817	mg/kg
TM-331	Total Tocopherols	3003	mg/kg

Tocopherols were determined by HPLC with a fluorescence detector using a method based on ISO 9936 :2016.

TM-252	Cholesterol	13.1	%
TM-252	Brassicasterol	5.6	%
TM-252	Campesterol	3.8	%
TM-252	Stigmasterol	19.6	%
TM-252	Δ-7-Campesterol	0.3	%
TM-252	Δ-5, 23-Stigmastadienol	1.6	%
TM-252	Chlerosterol	20.3	%
TM-252	β-Sitosterol	14.8	%
TM-252	Δ-5-Avenasterol	1.3	%
TM-252	Δ-5,24-Stigmastadienol	8.9	%
TM-252	Δ-7-Stigmastenol	7.3	%
TM-252	Δ-7-Avenasterol	3.3	%
TM-252	Total Sterols	705	mg/kg

Total sterols were determined by Gas Chromatography using a method based on the Official Journal of the European Communities method for analysis of sterols in olive oil. Very low levels of sterols were detected in the samples.

	EPA	15.4	mg/g
	EPA	15.1	mg/g

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-1** Your Refs: 96914 DH 5750
Description: DHA Algal Oil

Method	Analysis	Result	Units
	DHA	430.6	mg/g
	DHA	430	mg/g

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-2** Your Refs: 96915 DH 5751
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C12:0	0.9	%
	C13:0(I)	0.1	%
	C14:0	9.7	%
	C15:0	0.5	%
	C16:0	22.3	%
	C16:1	2.9	%
	C17:0	0.2	%
	C18:0	0.8	%
	C18:1(cis)	6.1	%
	C18:2(cis)	0.6	%
	C18:3(alpha)	0.2	%
	C20:0	0.1	%
	C20:1	0.4	%
	C22:1	0.5	%
	C24:0	0.1	%
	C20:3 (n6)	0.1	%
	C20:4 (n6)	0.3	%
	C20:5 (n3)	1.7	%
	C22:6 (n3)	44.2	%
	C22:5 (n6)	7.8	%
	C22:5 (n3)	0.4	%
Normalised fatty acid profile (%).			
TM-331	alpha tocopherol	536	mg/kg
TM-331	beta tocopherol	93	mg/kg

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-2** Your Refs: 96915 DH 5751
Description: DHA Algal Oil

Method	Analysis	Result	Units
TM-331	gamma tocopherol	1395	mg/kg
TM-331	delta tocopherol	743	mg/kg
TM-331	Total Tocopherols	2767	mg/kg

Tocopherols were determined by HPLC with a fluorescence detector using a method based on ISO 9936 :2016.

TM-252	Cholesterol	13.7	%
TM-252	Brassicasterol	4.0	%
TM-252	Campesterol	4.2	%
TM-252	Stigmasterol	14.1	%
TM-252	Δ-7-Campesterol	0.9	%
TM-252	Δ-5, 23-Stigmastadienol	1.3	%
TM-252	Chlerosterol	15.8	%
TM-252	β-Sitosterol	16.0	%
TM-252	Δ-5-Avenasterol	2.9	%
TM-252	Δ-5,24-Stigmastadienol	10.4	%
TM-252	Δ-7-Stigmastenol	13.1	%
TM-252	Δ-7-Avenasterol	3.7	%
TM-252	Total Sterols	1020	mg/kg

Total sterols were determined by Gas Chromatography using a method based on the Official Journal of the European Communities method for analysis of sterols in olive oil. Very low levels of sterols were detected in the samples.

	EPA	16.2	mg/g
	EPA	16.4	mg/g
	DHA	428.2	mg/g
	DHA	428.2	mg/g

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Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-3** Your Refs: 96916 DH 5752
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C12:0	0.9	%
	C13:0(I)	0.1	%
	C14:0	9.8	%
	C14:1	0.1	%
	C15:0	0.3	%
	C16:0(I)	0.1	%
	C16:0	18.5	%
	C16:1	6.6	%
	C17:0	0.1	%
	C18:0	0.7	%
	C18:1(trans)	0.1	%
	C18:1(cis)	10.3	%
	C18:2(cis)	0.5	%
	C18:3(alpha)	0.2	%
	C20:0	0.1	%
	C20:1	0.6	%
	C22:1	0.4	%
	C24:0	0.1	%
	C20:3 (n6)	0.1	%
	C20:4 (n6)	0.2	%
	C20:5 (n3)	1.5	%
	C22:6 (n3)	41.1	%
	C22:5 (n6)	7.2	%
	C22:5 (n3)	0.3	%

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Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-3** Your Refs: 96916 DH 5752
Description: DHA Algal Oil

Method	Analysis	Result	Units
Normalised fatty acid profile (%).			
TM-331	alpha tocopherol	530	mg/kg
TM-331	beta tocopherol	90	mg/kg
TM-331	gamma tocopherol	1504	mg/kg
TM-331	delta tocopherol	775	mg/kg
TM-331	Total Tocopherols	2899	mg/kg
Tocopherols were determined by HPLC with a fluorescence detector using a method based on ISO 9936 :2016.			
TM-252	Cholesterol	11.7	%
TM-252	Brassicasterol	6.3	%
TM-252	Campesterol	3.4	%
TM-252	Stigmasterol	24.0	%
TM-252	Δ-7-Campesterol	0.4	%
TM-252	Δ-5, 23-Stigmastadienol	1.7	%
TM-252	Chlerosterol	17.0	%
TM-252	β-Sitosterol	19.1	%
TM-252	Δ-5-Avenasterol	3.2	%
TM-252	Δ-5,24-Stigmastadienol	6.0	%
TM-252	Δ-7-Stigmastenol	5.2	%
TM-252	Δ-7-Avenasterol	1.9	%
TM-252	Total Sterols	1210	mg/kg
Total sterols were determined by Gas Chromatography using a method based on the Official Journal of the European Communities method for analysis of sterols in olive oil. Very low levels of sterols were detected in the samples.			
	EPA	14.3	mg/g

Science With Service

Approved By:
Aurelia Laluc
Senior Scientist I
(Investigative Analysis)

24 April 2018

(b) (6)

275753

READING SCIENTIFIC SERVICES LTD
Reading Science Centre, Whiteknights Campus
Pepper Lane, Reading, RG6 6LA
Tel: +44 (0)118 918 4000
Fax: +44 (0)118 9868932
email: enquiries@rssl.com
web: www.rssl.com

Certificate of Analysis

Ms Edith Von Kries
Cognis GmbH & Co.KG
Standort Illertissen
1 Robert-Hansen-Strasse
D- 89257 Illertissen
Germany

Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-3** Your Refs: 96916 DH 5752
Description: DHA Algal Oil

Method	Analysis	Result	Units
	EPA	14.6	mg/g
	DHA	394.4	mg/g
	DHA	394.8	mg/g

Science With Service

Approved By:
Aurelia Laluc
Senior Scientist I
(Investigative Analysis)

24 April 2018

(b) (6)

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Cognis GmbH & Co.KG
Standort Illertissen
1 Robert-Hansen-Strasse
D- 89257 Illertissen
Germany

Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-4** Your Refs: 96917 0016888247
Description: DHA Algal Oil

Method	Analysis	Result	Units
	C12:0	1.0	%
	C13:0(I)	0.1	%
	C13:0	0.1	%
	C14:0	10.2	%
	C14:1	0.1	%
	C15:0	0.5	%
	C16:0	22.3	%
	C16:1	3.9	%
	C17:0	0.2	%
	C18:0	0.8	%
	C18:1(cis)	7.1	%
	C18:2(cis)	0.6	%
	C18:3(alpha)	0.2	%
	C20:0	0.1	%
	C20:1	0.5	%
	C22:1	0.5	%
	C24:0	0.1	%
	C20:3 (n6)	0.1	%
	C20:4 (n6)	0.3	%
	C20:5 (n3)	1.7	%
	C22:6 (n3)	41.7	%
	C22:5 (n6)	7.7	%
	C22:5 (n3)	0.3	%

Normalised fatty acid profile (%).

Science With Service

Approved By:
Aurelia Laluc
Senior Scientist I
(Investigative Analysis)

24 April 2018

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Certificate of Analysis

Ms Edith Von Kries
Cognis GmbH & Co.KG
Standort Illertissen
1 Robert-Hansen-Strasse
D- 89257 Illertissen
Germany

Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-4** Your Refs: 96917 0016888247
Description: DHA Algal Oil

Method	Analysis	Result	Units
TM-331	alpha tocopherol	484	mg/kg
TM-331	beta tocopherol	84	mg/kg
TM-331	gamma tocopherol	1573	mg/kg
TM-331	delta tocopherol	693	mg/kg
TM-331	Total Tocopherols	2833	mg/kg

Tocopherols were determined by HPLC with a fluorescence detector using a method based on ISO 9936 :2016.

TM-252	Cholesterol	29.8	%
TM-252	Brassicasterol	3.9	%
TM-252	Campesterol	4.8	%
TM-252	Stigmasterol	13.7	%
TM-252	Δ-7-Campesterol	0.5	%
TM-252	Δ-5, 23-Stigmastadienol	0.9	%
TM-252	Chlerosterol	9.6	%
TM-252	β-Sitosterol	21.1	%
TM-252	Sitostanol	2.4	%
TM-252	Δ-5-Avenasterol	1.4	%
TM-252	Δ-5,24-Stigmastadienol	5.2	%
TM-252	Δ-7-Stigmastenol	5.1	%
TM-252	Δ-7-Avenasterol	1.6	%
TM-252	Total Sterols	2843	mg/kg

Total sterols were determined by Gas Chromatography using a method based on the Official Journal of the European Communities method for analysis of sterols in olive oil.

	EPA	16.1	mg/g

Science With Service

Approved By:
Aurelia Laluc
Senior Scientist I
(Investigative Analysis)

24 April 2018

(b) (6)

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Certificate of Analysis

Ms Edith Von Kries
Cognis GmbH & Co.KG
Standort Illertissen
1 Robert-Hansen-Strasse
D- 89257 Illertissen
Germany

Report No: P18-02696
Purchase Order: 4943217109
Date Received: 4th April 2018
Date Started: 16th April 2018

Analysis of Algal Oil

Sample Code: **P18-02696-4** Your Refs: 96917 0016888247
Description: DHA Algal Oil

Method	Analysis	Result	Units
	EPA	16.1	mg/g
	DHA	397.1	mg/g
	DHA	398	mg/g

EPA & DHA were determined using a method based on EP method 2.4.29 and the levels were calculated as mg/g and reported as triglycerides.

Science With Service

Approved By:
Aurelia Laluc
Senior Scientist I
(Investigative Analysis)

24 April 2018

(b) (6)

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January 22, 2020

Dear Dr. Downey,

Please find attached the results of microbiological testing (i.e., *Enterobacteriaceae* and *Cronobacter)* of algal oil powder requested in your email questions of November 26, 2019. Please let us know if you have any further needs.

Best regards,

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc.
phone: 630.352.0303
email: dschmitt@toxstrategies.com

eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAF64490
Eurofins Sample Number: DA19AA5257-1
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006211

Eurofins Sample Number DA19AA5257-1

Original Received Date:	17-Dec-2019
Description:	DHA 11% A KSH B DK13 Material number: 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0021735796

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Dec-2019			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Dec-2019			

Sample Compliance Assessment

DA19AA5257-1 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 20-Dec-2019 14:01:22 UTC+01:00

eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAF64486
Eurofins Sample Number: DA19AA5257-2
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006211

Eurofins Sample Number DA19AA5257-2

Original Received Date:	17-Dec-2019
Description:	DHA 11% A KSH B DK13 Material number: 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0021735796

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Dec-2019			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Dec-2019			

Sample Compliance Assessment

DA19AA5257-2 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 20-Dec-2019 14:01:17 UTC+01:00

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Certificate of Analysis

Analytical Report: AAF64485
Eurofins Sample Number: DA19AA5257-3
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006211

Eurofins Sample Number DA19AA5257-3

Original Received Date:	17-Dec-2019
Description:	DHA 11% A KSH B DK13 Material number: 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0021735796

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Dec-2019			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Dec-2019			

Sample Compliance Assessment

DA19AA5257-3 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 20-Dec-2019 14:01:20 UTC+01:00

Certificate of Analysis

Analytical Report: AAF64489
Eurofins Sample Number: DA19AA5257-4
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006211

Eurofins Sample Number DA19AA5257-4

Original Received Date:	17-Dec-2019
Description:	DHA 11% A KSH B DK13 Material number: 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0019196945

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Dec-2019			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Dec-2019			

Sample Compliance Assessment

DA19AA5257-4 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 20-Dec-2019 14:01:15 UTC+01:00

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Certificate of Analysis

Analytical Report: AAF64487
Eurofins Sample Number: DA19AA5257-5
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006211

Eurofins Sample Number DA19AA5257-5

Original Received Date:	17-Dec-2019
Description:	DHA 11% A KSH B DK13 Material number: 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0019196945

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Dec-2019			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Dec-2019			

Sample Compliance Assessment

DA19AA5257-5 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 20-Dec-2019 14:01:24 UTC+01:00

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Certificate of Analysis

Analytical Report: AAF64488
Eurofins Sample Number: DA19AA5257-6
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006211

Eurofins Sample Number DA19AA5257-6

Original Received Date:	17-Dec-2019
Description:	DHA 11% A KSH B DK13 Material number: 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0019196945

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Dec-2019			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Dec-2019			

Sample Compliance Assessment

DA19AA5257-6 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 20-Dec-2019 14:01:13 UTC+01:00

eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAG01130
Eurofins Sample Number: DA20AA0539-1
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006212

Eurofins Sample Number DA20AA0539-1

Original Received Date:	16-Jan-2020
Description:	DHA 11% A KSH B DK13, Material no. 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0021735793 (326196)

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Jan-2020			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Jan-2020			

Sample Compliance Assessment

DA20AA0539-1 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 22-Jan-2020 15:34:18 UTC+01:00

eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAG01128
Eurofins Sample Number: DA20AA0539-2
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006212

Eurofins Sample Number DA20AA0539-2

Original Received Date:	16-Jan-2020
Description:	DHA 11% A KSH B DK13, Material no. 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0021735793 (326196)

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Jan-2020			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Jan-2020			

Sample Compliance Assessment

DA20AA0539-2 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 22-Jan-2020 15:34:21 UTC+01:00

eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAG01129
Eurofins Sample Number: DA20AA0539-3
Version: 1

BASF A/S
Malmparken 5
2750 Ballerup
DK

Client Account Number: APH002145
Eurofins Quote Number: DNSN2013006212

Eurofins Sample Number DA20AA0539-3

Original Received Date:	16-Jan-2020
Description:	DHA 11% A KSH B DK13, Material no. 11001001
Containers Submitted:	1 Unit(s)
Client Sample ID:	0021735793 (326196)

Analysis	Specification	Result	Unit
Cronobacter spp.	Absent	Absent	/10 g
Method: ISO 22964 Analysis Date: 17-Jan-2020			
Enterobacteriaceae	Absent	Absent	/10 g
Method: ISO 21528-1 Analysis Date: 17-Jan-2020			

Sample Compliance Assessment

DA20AA0539-3 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information

When testing for Cronobacter spp. it is including Cronobacter sakazakii.

Contracted Company: Eurofins BioPharma Product Testing Denmark A/S

Ørnebjergvej 1, 2600 Glostrup, Denmark
pharma@eurofins.dk

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Data Reviewer Approval by
Tina Bonlokke, Senior Technician
for Eurofins Biopharma Product Testing Denmark A/S, on 22-Jan-2020 15:34:16 UTC+01:00

From: Don Schmitt
To: Downey, Jason
Cc: Haresh P Madeka
Subject: Re: GRN 862 - Request for Clarification
Date: Wednesday, May 6, 2020 8:47:18 AM
Attachments: image002.png

Hi Jason,

The intended use of BASF's algal oil is substitutional for existing uses of other DHA-containing oils and the cumulative exposure to DHA is not expected to increase as a result of the intended uses described in GRN 862.

I hope this clarifies the intake issue.

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540
phone: 630.352.0303
email: dschmitt@toxstrategies.com

From: "Downey, Jason" <Jason.Downey@fda.hhs.gov>
Date: Tuesday, May 5, 2020 at 3:27 PM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 862 - Request for Clarification

Hi Don,

In reviewing the record for GRN 862 (BASF's DHA algal oil), we noted a need for clarification:

In the dietary exposure section of your original notice and in your December 11, 2019 response to our question #2, you state that the maximum dietary exposures to DHA and the combination of DHA and EPA from the intended uses of algal oil in the foods listed in 184.1472(a)(3) are 1.5 g DHA/p/d and 3.0 g DHA+EPA/p/d, respectively. You also state in the original notice that the intended uses of algal oil are identical to uses of other GRAS DHA and/or EPA products. It is not clear whether the cumulative exposure to DHA will increase as a result of the intended uses of BASF's algal oil. Please indicate whether the intended use of BASF's algal oil is substitutional for existing uses of other DHA-containing oils and whether the cumulative exposure to DHA is expected to increase as a result of the intended uses described in GRN 862.

Please let me know if you have any questions.

Thanks,

Jason

Jason Downey, PhD
Regulatory Review Scientist
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
jason.downey@fda.hhs.gov

From:	Don Schmitt
To:	Downey, Jason
Cc:	Haresh P Madeka
Subject:	Re: GRN 862 - Clarification Needed
Date:	Tuesday, May 26, 2020 1:49:35 PM
Attachments:	image002.png

Hi Jason,

The *Schizochytrium* sp. strain ONC-T18 used to produce the BASF's DHA-rich algal oil is non-pathogenic.

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540
phone: 630.352.0303
email: dschmitt@toxstrategies.com

From: "Downey, Jason" <Jason.Downey@fda.hhs.gov>
Date: Tuesday, May 26, 2020 at 11:26 AM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 862 - Clarification Needed

RE: GRN 862 – BASF's DHA algal oil

Hi Don,
I apologize for the late-breaking request. We have one additional request for information:
Notices usually state or demonstrate that the microbe strain in a notice is non-toxicogenic and non-pathogenic. Between the batch data on toxins and statements referencing other material, there was enough in the notice to get at a lack of toxins. The same wasn't there for pathogenicity.
For the administrative record, please clarify whether *Schizochytrium* sp. strain ONC-T18 is non-pathogenic.
Let me know if you have any questions.
Thank you!
Jason

Jason Downey, PhD
Regulatory Review Scientist
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
jason.downey@fda.hhs.gov