GRAS Determination of Sunflower Lecithin for Use in Food

JANUARY 9, 2019

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GRAS Determination of Sunflower Lecithin for Use in Food

SUBMITTED BY:

Sternchemie GmbH & Co. KG
An der Alster 81
20099 Hamburg, Germany

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

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January 9, 2019

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Acronyms

ADME	absorption, distribution, metabolism, and excretion
AGPC	α-glycerylphosphorylcholine
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
cfu	colony-forming units
cGMP	current Good Manufacturing Practices
CIR	Cosmetic Ingredient Review
COA	Certificate of Analysis
EFSA	European Food Safety Authority
EPL	essential phospholipid
EU	European Union
FCC	Food Chemicals Codex
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food Drug and Cosmetic Act
FOIA	Freedom of Information Act
GM	genetically modified
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
IP	identity protected
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NOAEL	no-observed-adverse-effect level
OECD	Organisation for Economic Co-operation and Development
PAS	phosphatidic acid complex
PI	Phosphatidylinositol
SCF	European Commission Scientific Committee for Food
SCOGS	Scientific Committee on GRAS Substances
WHO	World Health Organization

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

(1) GRAS Notice Submission

Sternchemie GmbH & Co. KG (Sternchemie), through its agent, ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the submission of a Generally Recognized as Safe (GRAS) notice for the use of sunflower lecithin in foods for human consumption in accordance with Subpart E of 21 CFR § 170.

(2) Name and Address

Sternchemie GmbH & Co. KG
An der Alster 81
20099 Hamburg, Germany

(3) Name of Notified Substance

The name of the substance that is the subject of this GRAS determination is sunflower lecithin, a food ingredient composed of a complex mixture of phospholipids, glycolipids, carbohydrates, and triglycerides.

(4) Intended Use in Food

Sunflower lecithin is intended for use as an emulsifier, dispersing agent, wetting agent, and as a release agent in foods.

(5) Statutory Basis for GRAS Determination

Sternchemie, through its agent ToxStrategies, Inc., hereby notifies FDA of the submission of a GRAS notice for sunflower lecithin, which meets the specifications described herein and has been determined to be GRAS through scientific procedures in accordance with § 170.30(a) and (b).

(6) Premarket Approval Statement

Sternchemie further asserts that the use of sunflower lecithin in food, including nonexempt infant formula, as described below, is exempt from the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act, based on a conclusion that the notified substance is GRAS under the conditions of its 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 to the FDA on request and are also available for the FDA's review and/or copying during customary business hours from ToxStrategies, Inc., Naperville, IL.

(8) Data and Information Confidentiality Statement

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

(9) GRAS Notice Certification

To the best of our knowledge, the GRAS notice is a complete, representative, and balanced submission. Sternchemie is not aware of any information that would be inconsistent with a finding that the proposed use of sunflower lecithin in food, including non-exempt infant formula that meets appropriate specifications and is used according to current Good Manufacturing Practices (cGMP), is GRAS. In addition, recent reviews of the scientific literature indicated no concerns for potential adverse health effects.

(10) Name/Position of Notifier

[redacted]

May 18 2020

Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Sternchemie

Date

(11) FSIS Statement

Sternchemie's sunflower lecithin product is intended for use as an alternative source of lecithin in all currently approved food categories, including as an emulsifying agent in meat and poultry in compliance with 9 CFR § 424.21.

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

Identity

The sunflower lecithin product that is the subject of this GRAS determination is composed of a complex mixture of phospholipids, glycolipids, carbohydrates, and triglycerides. Sternchemie uses sunflower seeds to produce sunflower lecithin in three forms: standardized lecithin, hydrolyzed lecithin, and de-oiled (powdered) lecithin.

Sunflower standardized lecithin is a viscous fluid with a brown appearance. It is soluble in hexane, toluene, in addition to oils and fats. Sunflower hydrolyzed lecithin is a viscous fluid with a brown appearance. It is soluble in hexane, toluene, in addition to oils and fats and dispersible in water. Sunflower de-oiled lecithin is a powder with a greyish-yellow to greyish-brown appearance.

Lecithin is a natural complex mixture of acetone-insoluble phospholipids that consists mainly of phosphatidylcholine, phosphatidylethanolamine, phosphatidylinositol, and phosphatidic acid, as well as various amounts of other substances, such as triglycerides, fatty acids, and carbohydrates.

Empirical Formula and Chemical Structure of Lecithin

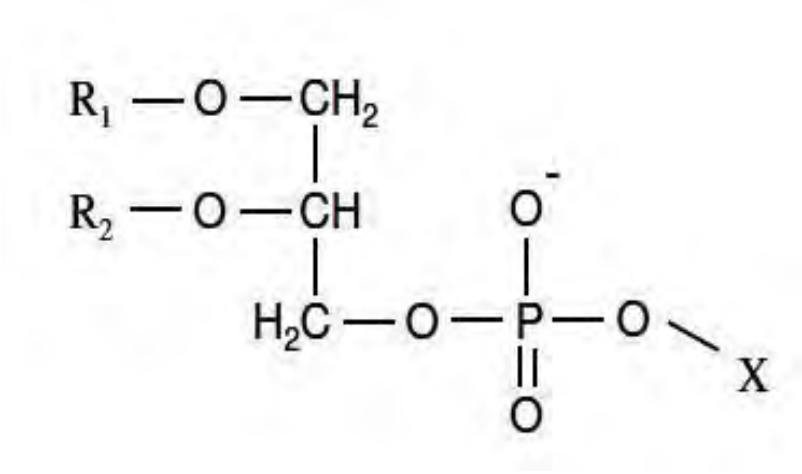

Figure 1. Typical chemical structure of lecithin

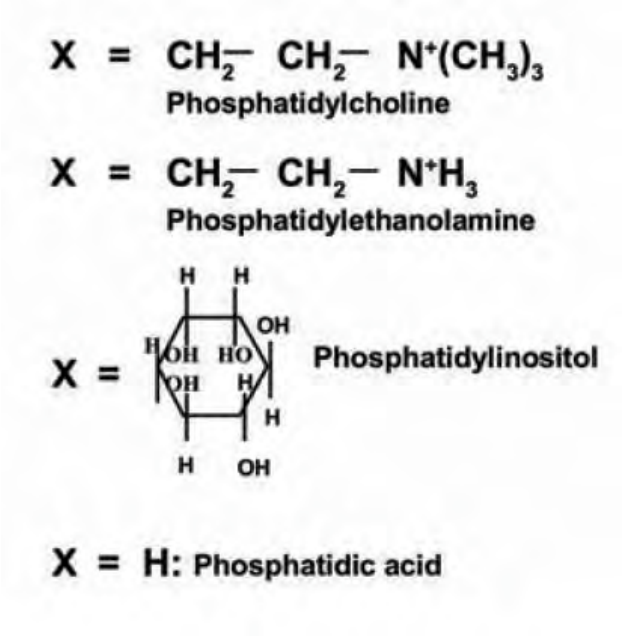

Figure 2. Structures of the main phospholipids of sunflower lecithin (van Nieuwenhuyzen, 2014)

Common or Chemical Names

The proposed common name for this product is sunflower lecithin. The CAS number for lecithins is 8002-43-5. The CAS number for hydrolyzed lecithins is 85711-58-6. The trade names of Sternchemie's sunflower lecithin product are LeciStar S (sunflower standardized lecithins), SternPhil S (sunflower hydrolyzed lecithins), and SternPur SP (sunflower de-oiled lecithin).

Manufacturing Process

Sunflower seeds are the starting material for Sternchemie's sunflower lecithin that is the subject of this GRAS self-determination. It is manufactured according to steps presented in the flow diagram below (Figure 3). Sternchemie processes crude lecithin to produce standardized, de-oiled (powder), or hydrolyzed sunflower lecithin product forms.

Processing of Sunflower Lecithin

Step 1: Crude oil production

In general, the production of sunflower crude lecithin shown in the flow chart (Figure 3) is very similar to the production processes of other vegetable lecithins, such as soy or rapeseed lecithin.

After internal quality approval, sunflower seeds go through the following standard processes: cleaning, drying, tempering, conditioning, de-hulling (partial removal of husk by crushing) and pressing. The remaining oil in the press cake is removed by extraction

with a food-grade solvent (hexane; 21 CFR § 173.270). This process step includes continuous spraying of hexane on the press cake while the press cake is moving on a conveyor belt. The solvent passes through the matter, extracting the remaining oil. The mix of the solvent and extracted oil (miscella) collects on the bottom of the extractor. The most commonly used extractors are baskets with a continuous-loop design.

After extraction, the miscella is usually filtered by hydrocyclones or by bag filters with a mesh size of 80–100 µm to remove the major part of solid impurities. In the final step, the solvent remaining in the miscella evaporates by use of steam stripping. The solvent-free crude sunflower oil then moves to the next step—degumming.

Step 2: Degumming

Crude oil is de-gummed by addition of 1%–2% water, to remove water-hydratable phosphatides. After 30 to 60 minutes of continuous stirring at 70–80°C, the polar lipids hydrate, become insoluble in oil, and precipitate. This so-called lecithin sludge, or wet gums, can be separated from the oil by centrifugation. The gums consist of 30%–60% water, phospholipids and glycolipids, triglycerides, carbohydrates, traces of sterols, free fatty acids, and carotenoids. Crude sunflower lecithin is obtained after water removal by vacuum drying using a thin-layer evaporator or a vacuum drum.

Step 3: Standardization

Depending on the process conditions and also on the raw material geographical source, weather conditions, and other factors, the composition of the crude lecithin, especially the ratio between the polar lipids (phospholipids, glycolipids etc. = acetone insoluble matter) and the unipolar lipids (triglycerides, fatty acids etc. = acetone soluble matter) can vary. These variations can have an effect on the functionality of lecithin in the final application. Therefore, it is recommended to standardize the crude lecithin in order to produce a consistent composition and functionality.

The standardization of crude sunflower lecithin is usually accomplished by addition of sunflower oil or/and sunflower-based oleic fatty acids.

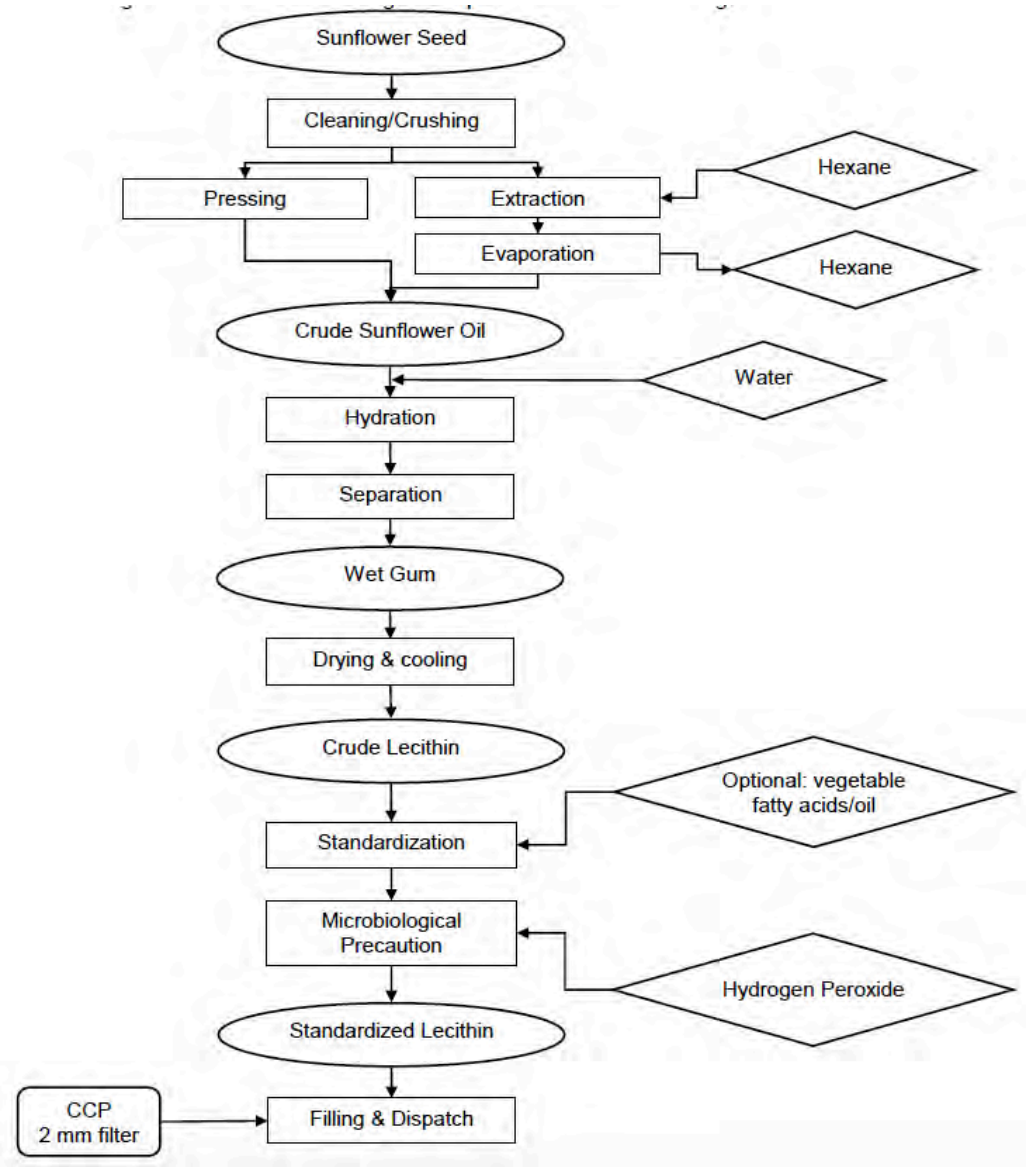

Figure 3. Manufacturing process flow diagram for LeciStar (standardized sunflower lecithin)

Manufacturing Process for De-oiled Lecithin (Powder)

Crude sunflower lecithin contains approximately 45%–50% polar lipids, which are the functionally active components, and 35%–40% neutral lipids, predominantly triglycerides. To improve the functional properties—for example, their dispersibility, as well as the handling of the viscous crude lecithins—the ratio of polar lipids must be increased by removing the neutral lipids via the "de-oiling process". The most common method for the production of oil-free vegetable lecithins is extraction with acetone. The acetone-based extraction process is based on the property of polar lipids being almost insoluble in acetone, whereas neutral lipids dissolve easily.

In the first step, crude lecithin is mixed with acetone by continuous stirring. Then acetone is removed by centrifugation. The solvent residue is removed by gentle drying. The extraction leads to products in powder or granulated form that contain a residual content of approximately 2%–3% of neutral lipids (Figure 4). These products display a significant improvement in emulsifying capacity and in dispersibility in water. A free-flowing agent (i.e., silicon dioxide) may be added as necessary.

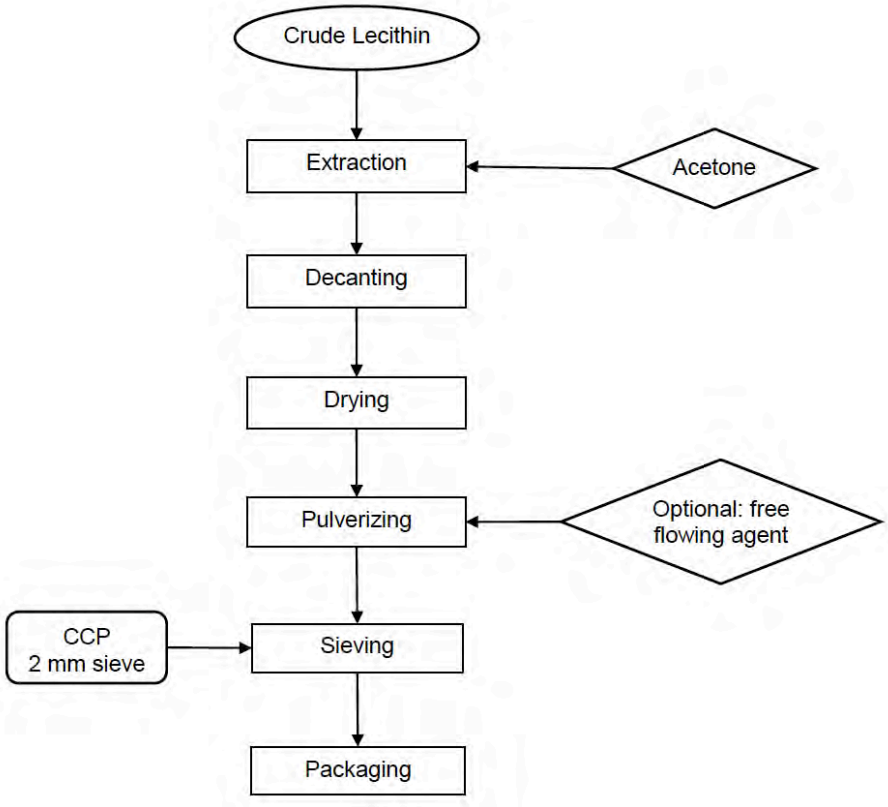

Figure 4. Manufacturing process flow diagram for SternPur (de-oiled sunflower lecithin)

Manufacturing Process for Hydrolyzed Sunflower Lecithin

Chemical and physical properties of phospholipids depend on their molecular structures. For certain final applications, the original structure, and consequently the physicochemical and nutritional properties, of phospholipids can be modified by enzymatic hydrolysis. The enzyme phospholipase A2 (Maxapal A2®; DSM) catalyzes hydrolytic cleavage of fatty acids at the sn-2 position to produce lyso-phospholipids. The resulting lecithin is a mix of original phospholipids (with two fatty acids) and lyso-phospholipids (with one fatty acid). Hydrolyzed sunflower lecithin shows improved emulsifying properties. Phospholipase A2 used for hydrolysis is a food-grade enzyme derived from non-genetically modified microorganisms.

Depending on the ratio between the original and lyso-phospholipids, sunflower lecithins with high-and-low degrees of hydrolysis can be differentiated. The degree of hydrolysis is

usually defined as the amount of lyso-phospholipids divided by total phospholipids (original and lyso-phospholipids). The phospholipid composition can be analyzed either by thin-layer chromatography or by 31P-NMR.

The production process includes mixing the crude or standardized sunflower lecithin with a water solution of Phospholipase A2 under controlled processing conditions (temperature, mixing time). The required degree of hydrolysis can be achieved by adjustment of processing conditions. After completion of the hydrolysis, water is removed by vacuum drying and heating which inactivates the enzyme (Figure 5).

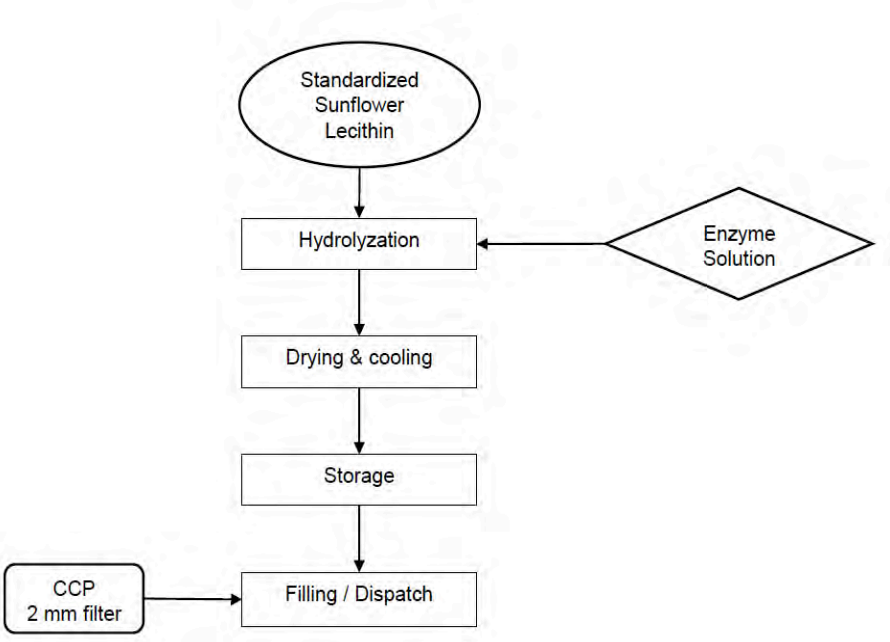

Figure 5. Manufacturing process flow diagram for SternPhil (hydrolyzed sunflower lecithin)

The regulatory status and approvals of reagents/processing aids used in the manufacture of sunflower lecithin are listed in Table 1 below. They are commonly used in food additive/ingredient manufacturing processes.

Phospholipase A2 Enzyme (Maxapal® A2)

MAXAPAL® A2 (product of DSM) is a liquid phospholipase A2 obtained by submerged culture of a selected strain of *Aspergillus niger*. The main activity of MAXAPAL® A2 is phosphatide-2-acyl-hydrolase (EC.3.1.1.4). MAXAPAL® A2 hydrolyzes phospholipids, by specifically cleaving fatty acids from the second position on the glycerol moiety of the phospholipid (PL), resulting in a lyso-phospholipid plus a fatty acid.

DSM's phospholipase A2 enzyme was the subject of GRN 183 and received a letter of no objection on May 11, 2006. The GRN and a subsequent supplement to the GRN informed FDA of the view of DSM that PLA2 (porcine) enzyme preparation from *A. niger* was GRAS, through scientific procedures, for use as an enzyme for the hydrolysis of phospholipids in baked goods and egg yolk-based sauces and dressings at levels not to

exceed good manufacturing practices and for degumming oils at 30-60 milligrams Total Organic Solids per kilogram of raw material (subject of GRN supplement; letter of no objection dated November 18, 2014).

As stated in GRN 183 (FDA, 2006a), "because phospholipase A2 is an enzyme protein naturally occurring in both animals and plants, it is expected to be digested as would any other protein occurring in food. It is one of the digestive enzymes present in the pancreatic juice of mammals, including humans (de Haas et al., 1968; Rossiter, 1968; Johnson and McDermott, 1974), and the phospholipids that form the substrates for phospholipase A2 are natural constituents of various foods."

A. niger is not a human pathogen and is not toxigenic. It is known to naturally occur in foods and is commonly present in products like rice, seeds, nuts, olives and dried fruits. *A. niger* has been safely used in the commercial production of organic acids and various food enzymes, such as glucose oxidase, pectinase, alpha-amylase and glucoamylase for decades. As reviewed in GRN 183 (FDA, 2006a), specific tests have been performed to confirm that the recombinant phospholipase A2 production strain is not able to produce any toxins under fermentation conditions, nor under conditions that are known to induce toxin production in general. The results of these tests showed that the production strain does not produce any known toxins under these conditions.

The enzyme preparation phospholipase A2 derived from *A. niger* strain PLA-54, overexpressing the phospholipase A2 gene from porcine pancreas, has been evaluated according to the Pariza & Johnson Decision Tree (2001). To confirm the assumption that phospholipase A2 would not have any toxic properties and to further establish the toxicological safety of the use of phospholipase from *A. niger* in food, DSM conducted the following list of additional safety studies:

- Acute oral toxicity 2x
- Subacute (14-day) oral toxicity study
- Subchronic (90-day) oral toxicity study
- Ames test
- Chromosomal aberration, *in vitro*
- Micronucleus mice, *in vivo*

No adverse effects or mutagenic activity were observed in the studies as summarized in GRN 183 (FDA, 2006a). DSM concluded that the study data was consistent with a long history of safe use of *A. niger* and phospholipase A2 in food processing and in the scientific literature. Based upon this information/data, as well as upon the limited and well characterized genetic modifications allowing for safe production of the enzyme preparations, DSM concluded that their phospholipase A2 preparation from *A. niger* (MAXAPAL® A2 enzyme; same as used in the production of sunflower hydrolyzed lecithin) was GRAS for the intended conditions of use.

Table 1. Reagents/processing aids — Sunflower lecithin

Reagent/Processing Aid	CAS Number	21 CFR Citation
Acetone	67-64-1	21 CFR §173.210
Hexane	7732-18-5	21 CFR §173.270
Phospholipase A2 derived from *Aspergillus niger* (MAXAPAL® A2)	9001-84-7	GRN 183
Hydrogen peroxide	7722-84-1	21 CFR §184.1366
Silicon dioxide	7631-86-9	21 CFR §172.480

Analyses of lots of the sunflower lecithin products for the presence of residual solvents (e.g., acetone, hexane) are all reported as <1 ppm (see Appendix A).

Product Specifications

The proposed food-grade specifications for Sternchemie's sunflower lecithin products are presented in Table 2, along with a comparison to the specifications published in the Food Chemicals Codex (FCC) 11th Edition. The specifications established for Sternchemie's sunflower lecithin product meet or exceed the published FCC specifications.

Table 2. Proposed specifications for sunflower lecithin products and comparison to FCC specifications

Parameter	FCC Specification for Lecithin	Sunflower Standardized Lecithin (LeciStar S 100, 200, 300)	Sunflower Hydrolyzed Lecithin (SternPhil S DH 40, 50)	Sunflower De-Oiled Lecithin (SternPur SP)
Chemical and Physical Specifications				
Acetone-Insoluble Matter (%)	NLT 50	NLT 60	NLT 56	NLT 96
Toluene-Insoluble Matter* (%)	NMT 0.3	NMT 0.3	NMT 0.3	NMT 0.3
Acid Value (mg KOH/g)	NMT 36	NMT 30	NMT 45	NMT 35
Peroxide Value (meq O_2/kg)	NMT 100	NMT 5	NMT 5	NMT 5
Moisture/Loss on Drying (%) (105°C, 1hr)	NMT 1.5	NMT 0.8	NMT 1	NMT 1.5
Lead (ppm)	NMT 1	NMT 1	NMT 1	NMT 1
Microbiological Specifications				
Aerobic mesophile total plate count	--	NMT 3000	NMT 3000	NMT 3000
Yeast (cfu/g)	--	NMT 100	NMT 100	NMT 100
Mold (cfu/g)	--	NMT 100	NMT 100	NMT 100
Escherichia coli (/g)	--	Negative	Negative	Negative
Salmonella (/25 g)	--	Negative	Negative	Negative

*FCC = Food Chemicals Codex; NLT = not less than; NMT = not more than.

Analytical results for additional select nutritional parameters are provided in Tables 3 and 4. The certificates of analysis (COAs) for the analytical results in Tables 3 and 4 can be found in Appendix A.

Table 3. Typical fatty acid analysis for sunflower lecithin products

Fatty Acid	LeciStar S 100 (Liquid Standardized)	SternPhil S DH (Liquid Hydrolyzed)	SternPur SP (De-Oiled)
Palmitic (C16:0)	11%–15%	11%–15%	14%–18%

Stearic (C18:0)	2%–5%	2%–5%	3%–5%
Oleic (C18:1)	13%–21%	13%–21%	12%–14%
Linoleic (C18:2)	56%–70%	56%–70%	62%–66%
Linolenic (C18:3)	1%–8%	1%–8%	2%–4%

Table 4. Typical phospholipid composition of sunflower lecithin

Phospholipids	**LeciStar S 100, 200, 300, 100T (Liquid Standardized)**	**SternPur SP (De-Oiled)**	**SternPhil S DH 40, 50 (Liquid Hydrolyzed)**
Phosphatidylcholine (PC)	12%–18%	19%–23%	8%–10%
Lyso-Phosphatidylcholine (LPC)	ND	ND	3%–7%
Phosphatidylinositol (PI)	10%–16%	15%–22%	6%–12%
Phosphatidylethanolamine (PE)	4%–8%	6-13%	3%–4%
Lyso-Phosphatidylethanolamine (LPE)	ND	ND	1%–3%
Phosphatidic Acid (PA)	1%–4%	2%–6%	1%–4%

ND = no data.

Comparisons of three non-consecutive lots of the liquid standard, liquid hydrolyzed, and de-oiled forms of Sternchemie's sunflower lecithin to the proposed specifications are provided in Tables 5, 6, and 7. The major difference lies in the specifications and analysis of the total phospholipid content reported as acetone insolubles. As illustrated in Tables 5, 6, and 7, the sunflower lecithin products consistently meet specifications, indicating a well-controlled, consistently manufactured product. All of Sternchemie's lecithin is manufactured according to cGMP, as defined in 21 CFR § 110 and § 117 Subpart B.

Table 5. Analytical data for three non-consecutive lots of sunflower standardized lecithin

Parameter		Lecithin (Standardized)		
	Sternchemie Specifications for Lecithin	**PSC019269**	**PSC021669**	**PSC021915**
Chemical and Physical Specifications				
Acetone Insolubles (%)	NLT 60	62.72	63.39	67.87
Toluene Insoluble Matter (%)	NMT 0.3	0.24	0.17	0.23
Moisture (%)	NMT 0.8	0.52	0.28	0.5
Peroxide Value (meq/kg)	NMT 5	0.0	0.59	0.0
Acid Value (mg KOH/g)	NMT 30	27.04	26.91	25.27
Lead (ppm)	NMT 1	<0.01	<0.01	<0.01
Microbiological Specification				
Aerobic mesophile total plate count (cfu/g)	NMT 3,000	<10	<10	<10
Yeast (cfu/g)	NMT 100	<10	<10	<10
Mold (cfu/g)	NMT 100	<10	<10	<10
Escherichia coli (/g)	Negative	Negative	Negative	Negative
Salmonella (/25 g)	Negative	Negative	Negative	Negative

ND = no data.

Table 6. Analytical data for three non-consecutive lots of sunflower hydrolyzed lecithin SternPhil S DH 50

Parameter		Lecithin (Hydrolyzed)		
	Sternchemie Specifications for Lecithin	**PSC019451**	**PSC020071**	**PSC022227**
Chemical and Physical Specifications				
Acetone Insolubles (%)	NLT 56	56.23	57.06	56.64
Toluene Insoluble Matter (%)	NMT 0.3	0.15	0.09	0.10
Moisture (%)	NMT 1	0.33	0.37	0.42
Peroxide Value (meq/kg)	NMT 5	0.4	0.0	0.0
Acid Value (mg KOH/g)	NMT 45	37.60	40.54	41.37
Lead (ppm)	NMT 1	<0.01	<0.01	<0.01
Microbiological Specification				
Aerobic mesophile total plate count (cfu/g)	NMT 3000	<10	<10	<10
Yeast (cfu/g)	NMT 100	<10	<10	<10
Mold (cfu/g)	NMT 100	<10	<10	<10
Escherichia coli (/g)	Negative	Negative	Negative	Negative
Salmonella (/25 g)	Negative	Negative	Negative	Negative

Table 7. Analytical data for three non-consecutive lots of sunflower de-oiled lecithin SternPur SP

Parameter	Sternchemie Specifications for Lecithin	Lecithin (De-Oiled)		
		PSC017108	PSC019616	PSC021836
Chemical and Physical Specifications				
Acetone Insolubles (%)	NLT 96	96.8	98.1	97.3
Moisture (%)	NMT 1.5	1.26	1.12	1.09
Peroxide Value (meq/kg)	NMT 5	0.2	0.9	0.0
Acid Value (mg KOH/g)	NMT 35	30.6	29.6	31.2
Lead (ppm)	NMT 1	0.01	0.02	0.01
Microbiological Specification				
Aerobic mesophile total plate count (cfu/g)	NMT 3000	60	650	150
Yeast (cfu/g)	NMT 100	<10	30	<10
Mold (cfu/g)	NMT 100	10	50	<10
Escherichia coli (/g)	Negative	Negative	Negative	Negative
Salmonella (/25 g)	Negative	Negative	Negative	Negative

In summary, the analytical (physical, chemical, and microbiological) results for sunflower lecithin summarized in the above tables as well as additional parameters are included in the COAs in Appendix A and confirm that the finished product meets the proposed analytical specifications and demonstrate the consistency of production.

Stability Data

The sunflower lecithin products described above meet Sternchemie's proposed analytical specifications. Appropriate stability testing has been conducted over a 12-month period and will continue for 24 months (Appendix B). The recommended storage conditions are as follows: store in a dry place, away from sunlight, at 15- 25°C, in original unopened packaging.

§ 170.235 Part 3, Dietary Exposure

Sunflower lecithin is intended for addition to foods as an emulsifier, wetting agent, as well as a release agent. According to 21 CFR § 184.1400, lecithin that is solvent extracted from soy, safflower, or corn oils can be used in food without limitation other than cGMPs. Sternchemie's sunflower lecithin is intended for use as an alternative source of lecithins to that derived from other plant sources.

Sternchemie's sunflower lecithin product is intended for use as an alternative source of lecithin in all currently approved food categories (including as an emulsifying agent in meat and poultry; 9 CFR § 424.21) in accordance with cGMP. As described in numerous GRAS Notifications (e.g., GRN No. 533 for canola lecithin), the typical uses of lecithin in foods include but are not limited to baked goods, dairy products, milk analog beverages, breakfast cereals, pasta, confections, soups, stews, chili, ice cream/frozen desserts, margarines/spreads, ovenable breadings and coatings, frostings, non-dairy creamer, sauces/gravies, and as a dietary source of choline in milk-based non-exempt infant formula for term infants at levels up to 3 grams (g) per 100 g. GRN 533 estimated the average dietary exposure to canola lecithin from the intended food uses and use levels to be 6.8–9.5 g per person per day (i.e., equivalent to 113–160 mg/kg bw/day for a 60-kg adult and 226–320 mg/kg bw/day for a 30-kg child). Regarding infant consumption, it is recommended that infants consume 2.5 ounces of formula for every pound of body weight (American Journal of Pediatrics, 2015). An infant weighing 10-15 pounds (approximately 2–3 months of age) would then consume approximately 25 ounces of formula per day (1 ounce equals 28.3 grams); equivalent to approximately 700 grams of formula per day. Based on proposed average and maximum incorporation of lecithin in infant formula of approximately 1 to 3 g/100 g of formula (similar to use levels of canola lecithin in GRN 533), intake of lecithin would range from 7 to 21 g/day or 1 to 3 g/kg bw/day for a 2- to 3-month old infant weighing approximately 7 kg.

In summary, the proposed uses of the sunflower lecithin product will not result in an increase in the overall consumption of lecithin, but simply will provide an alternative source of well-characterized lecithin from sunflower seeds for use in food. Therefore, cumulative intake analysis is not considered necessary.

§ 170.240 Part 4, Self-Limiting Levels of Use

The use of sunflower lecithin in foods is considered to be self-limiting for technological reasons, such as product texture and/or flavor profile, either of which could affect consumer acceptance.

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

While sunflower lecithin is currently used in food, the statutory basis for our conclusion of GRAS status in the notice is based on scientific procedures and not on common use in food.

§ 170.250 Part 6, GRAS Narrative

History of Use and Regulatory Approval of Sunflower Lecithin

The term lecithin was derived from the Greek word "λέκιθος" which means "egg, the start of life." Lecithin is a common phospholipid and is a common polar lipid that is important to support various functions in the body. Phospholipids can be found in all the cells of our body (van Nieuwenhuyzen, 2014). Lecithin was discovered in 1846, and industrial production began in the 1920s when an extraction process from plant sources was implemented.

Lecithin from soy, safflower, or corn is approved for use in food as stated in 21 CFR § 184.1400, and it can be used in food with no limitation other than cGMP.

> 21 CFR § 184.1400 Lecithin
>
> (a) Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils. Lecithin is bleached, if desired, by hydrogen peroxide and benzoyl peroxide and dried by heating.
>
> (b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 166-167, which is incorporated by reference.
>
> (c) In accordance with 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.
>
> (d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Numerous lecithin ingredients from various sources are recognized as GRAS for their intended uses in foods, and the lecithin ingredients listed in Table 8 have received letters of no objection from the Food and Drug Administration (FDA). Additionally, lecithin also comprises hydrolyzed products through the use of appropriate enzymes and enzyme-modified lecithin is also GRAS according to 21 CFR § 184.1063.

Table 8. Lecithin-related GRAS Notifications

GRN No.	Lecithin Product	Date of Closure
682	Lecithin from canola	07/07/17
545	Phosphatidylserine derived from sunflower lecithin	05/5/15
534	Hydrogenated lecithin from soy	12/22/14
533	Lecithin from canola	03/20/15
311	Phosphatidylserine produced through enzymatic transphosphatidylation of krill lecithin with L-serine	05/15/10
279	Fish phosphatidylserine manufactured from ethanol-extracted lecithin derived from herring and whiting fish biomass	07/25/09
226	Lecithin derived from krill	01/03/08
223	Phosphatidylserine manufactured from high phosphatidylcholine-enriched soybean lecithin	12/20/07
197	Soy lecithin enzymatically modified to contain approximately 90% percent phosphatidylserine	09/20/06
186	Soy lecithin enzymatically modified to contain increased phosphatidylserine	07/20/06
134	Soy protein hydrolysate with enzyme-modified lecithin	01/08/04

Safety

Introduction

Lecithin is a direct food substance affirmed as GRAS in 21 CFR § 184.1400, which states that "commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of othe[r] lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils." According to 21 CFR § 184.1400, lecithin from soy, safflower, or corn oils can be used in food with no limitation other than cGMP. Sunflower oil is being proposed as an alternative source of lecithin, and the sunflower lecithin that is the subject of the GRAS determination would be added to food in a manner similar to the oil sources cited in 21 CFR § 184.1400. The identity of the Sternchemie sunflower oil-derived lecithin is similar to the product (i.e., lecithin from canola) considered GRAS in GRN 533 and GRN 682 (FDA, 2015a, 2017), which received no questions from FDA, and are proposed for the same intended uses therein.

Enzyme-modified lecithin is also GRAS according to 21 CFR § 184.1063. Additional sources for or derivatives of lecithin that have been notified as GRAS to FDA with "no

questions" letters issued include krill-based (GRN 226; FDA, 2008), soy lecithin phosphatidylserine complex (GRN 186; FDA, 2006b, and GRN 197; FDA, 2006c), fish phosphatidylserine from lecithin from fish biomass (GRN 279; FDA, 2009), phosphatidylserine from krill lecithin (GRN 311; FDA, 2010); phosphatidylserine derived from sunflower lecithin or soy lecithin (GRN 545; FDA, 2015b), and soybean-derived hydrogenated lecithin (GRN 534; FDA, 2014). The differences in composition and/or source material of the various lecithin products are not expected to make a significant difference regarding potential toxicity. Thus, their determination as safe and GRAS for the intended use in specified foods, and the key data used to support these conclusions, are relevant to the assessment of sunflower-derived lecithin product. In addition, lecithin is approved for use as an emulsifying agent and antioxidant in oleomargarine, shortening, and various meat and poultry products in 9 CFR § 424.21.

As noted previously, the identity and composition of the Sternchemie sunflower lecithin is similar to that of other, approved lecithin products and consistent with the Food Chemicals Codex specifications (11th edition). Tables 9 and 10 below demonstrate that the phospholipid and fatty acid profile of sunflower-derived lecithin is not significantly different from approved lecithins included in the CFR or with those notified to FDA in GRNs.

Table 9. Main phospholipid profile of sunflower lecithin product compared to other sources of lecithin confirmed as GRAS

Phospholipid	Percent of Phospholipids (w/w%)					
	Sunflower Lecithin Product	**Canola Lecithin[A]**	**Soy Lecithin[B]**	**Krill Lecithin[C]**	**Corn Lecithin[D]**	**Canola Lecithin[E]**
Phosphatidylcholine	8-23	13–25	13–38	46–95	31	15–19
Phosphatidylethanolamine	3-13	6–14	8–23	36–85	3	7–9
Phosphatidylinositol	6-22	8–14	10–21	0–7	16	10–12
Phosphatidic Acid	1-6	1–7	2–16	NR	9	2–3

[A]GRN 533 crude canola lecithin product.
[B]GRN 682; Schofield, 1981; van Nieuwenhuyzen, 2014; Szuhaj, 1989
[C]GRN 226
[D]Szuhaj, 1989
[E]GRN 682
NR — not reported

Table 10. Main fatty-acid profile of sunflower lecithin product compared to other sources of lecithin confirmed as GRAS

Fatty Acid	Percent of Total Fatty Acids (w/w%)					
	Sunflower Lecithin Product	Canola Lecithin[A]	Soy Lecithin[B]	Krill Lecithin[C]	Corn Lecithin[D]	Canola Lecithin[E]
Palmitic (C16:0)	11-18	7–10	11–20	13–15	18	8
Stearic (C18:0)	2–5	1–3	3–6	0.7–0.9	2	1
Oleic (C18:1)	12-21	52–57	9–24	6–13	25	53–57
Linoleic (C18:2)	56-70	25–29	50–60	2	54	25–28
Linolenic (C18:3)	1-8	6–8	5–9	NR[F]	1	7–8

[A]GRN 533 crude canola lecithin product.
[B]van Nieuwenhuyzen, 2014; Szuhaj, 1989
[C]GRN 226
[D]Szuhaj, 1989
[E]GRN 682
[F]Source did not provide a value for this fatty acid.
NR — not reported

Safety Data

The safety of various lecithins for use in foods has been evaluated by several international organizations, all of which concluded that they are safe for human consumption. In 1973, the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974) evaluated lecithin and concluded the acceptable daily intake to be "not limited." The European Commission's Scientific Committee for Food (SCF) previously determined lecithins, including hydrolyzed lecithins to be safe for use in foods and infant formula (SCF, 1982, 1997). In 2015, the European Food Safety Authority (EFSA) issued a call for data on lecithins (E 322) to re-evaluate their use as additives to human foods in the European Union. No further information was identified (EFSA, 2015). In 2017, EFSA published a re-evaluation of lecithins (E 322) for use as food additives. The EFSA Panel on Food Additives and Nutrient Sources concluded that no safety concern exists regarding the use of lecithin as a food additive in individuals over 12 weeks of age based on its exposure assessment,[1] and that no numerical ADI was needed for the general population over 1 year of age (EFSA, 2017).

EFSA has also issued a Scientific Opinion regarding the safety and efficacy of lecithins for feed for all animal species, which stated, "Lecithins are natural constituents of plants and animal products, as components of biological components and as a nutritional reserve of

[1] The EFSA (2017) Panel did not include infants less than 12 weeks of age in the risk assessment and stated that the re-evaluation was not applicable to this subpopulation.

phospholipids (eggs, milk). Lecithins in animal products result from dietary sources and *de novo* synthesis. The metabolic fate of lecithins is common to all animal species, including humans, lysolecithins being intermediate metabolites. An accumulation in animal tissues and products is not expected. Therefore, the FEEDAP [Additives and Products or Substances used in Animal Feed] Panel concludes that the use of lecithins in animal nutrition does not pose any risk to the consumer" (EFSA, 2016).

Due to the extensive reviews that have been conducted on lecithins, the safety sections of more recent GRNs have been limited in the additional safety data that have been provided. As an example, GRNs 533 and 534 reviewed only more recent data on the phosphatidylcholine degradation product, α-glycerylphosphorylcholine (AGPC); these GRNs included acute, subchronic, and genetic toxicity (pp. 19-21 and 15-17 in GRNs 533 and 534, respectively). The safety section of GRN 226 (FDA, 2008; pages 8–11) addressed only potential differences in marine-derived phosphatidylcholine and associated lipids (focused on DHA and EPA) versus other approved phospholipids. No toxicity or additional safety data were discussed beyond that of the basic biochemistry of lecithin in the human body; the GRN noted that "the constituents of krill-based lecithin are commonly found in food" and provided no additional discussion.

The safety of lecithins has been evaluated repeatedly, but the data on which the safety conclusions of these evaluations were based varied widely. This variable approach is due to the composition and nature of lecithins. Given that lecithin is a mixture consisting of phospholipids (primarily phosphatidylcholine, phosphatidylethanolamine, phosphatidic acid, and phosphatidylinositol), fatty acids, and other minor components (e.g., triglycerides and carbohydrates), it is reasonable that an evaluation of any of these constituents is pertinent to a safety determination.

JECFA's (1974) evaluation included only a few studies of egg yolk phosphatides in animals and lecithin administration in humans. They concluded, "Although fewer toxicological studies have been conducted than would normally be required for substances used as food additives, it is considered that nutritional and clinical experience with lecithin is sufficiently extensive to compensate for the incompleteness of the experimental data."

In 1979, after consideration of a two-year feeding study of lecithin in rats (Brantom et al., 1973) and exposures in humans, the Select Committee on GRAS Substances (SCOGS) issued an opinion (SCOGS, 1979) on lecithin and hydrogen peroxide bleached lecithin. The SCF (1982) opinion on lecithin safety similarly included only a couple of studies on lecithin administration in rats. The EFSA Scientific Opinion on the safety and efficacy of lecithins for all animal species relied only on the data in CIR (2015) and a study on phospholipids to conclude, "The toxicological data on lecithins showed no effects of concern and no indication of genotoxicity and carcinogenicity." CIR (2015) provided a comprehensive review of the available toxicokinetic and toxicological literature on the class of lecithins in reaching its conclusion with regard to various compounds that included lecithin, lysolecithin, lysohosphatidic acid, phosphatidylserine, phosphatidylcholine, phosphatidylethanalomine, phosphatidylinositol, hydrogenated lecithin, and phosphatidic acid.

A thorough search of regulatory agency databases including FDA and EFSA was conducted. In addition, a detailed review of studies published more recently was conducted (limited to studies published in 2017–2019—the period of time since FDA's review of GRN 682, canola lecithin). This search identified no additional data relevant to the safety of the intended use of sunflower lecithin in food.

The key available items of information that were considered as part of this GRAS assessment for sunflower-derived lecithin are summarized below.

Absorption, Distribution, Metabolism, and Excretion (ADME)

Lecithins are naturally occurring components of cells in the human body. In addition, they are formed in the gastrointestinal tract as part of the normal digestion of food (EFSA, 2017). Dietary lecithin is generally well absorbed in humans, with the majority being incorporated into the surface coat of chylomicrons. A review of this process is provided by Grundy (1987) and is discussed in GRNs 226, 533, and 682, and EFSA (2016, 2017[2]).

After ingestion, a small amount of lecithin is absorbed intact in the small intestine, primarily the duodenum and upper jejunum. The majority of the remaining lecithin undergoes hydrolysis by pancreatic phospholipase A2, forming lysolecithins. The kinetics of this process occur fairly rapidly. In volunteers given 1-gram oral capsules of radiolabeled lecithin (3^H in choline and ^{14}C in two fatty-acid residues), labeled lipids were detected in blood samples at approximately 2 hours after administration, with peak blood levels measured at 4–12 hours (^{14}C) and 6–24 hours (^{3}H) post-dose (Zierenberg and Grundy, 1982). Blood samples taken at 24 hours post-dose showed that about three-fourths of the radioactivity was distributed in the plasma, with about one-fourth distributed in red blood cells. Once they are absorbed and hydrolyzed, lysolecithins and fatty acids are taken up by mucosal cells and can undergo different processes: (1) re-esterification with a fatty acid (the resulting lecithin can be used in normal biological functions, such as becoming part of cell membranes or coating chylomicrons), (2) complete lipolysis (the released fatty acids can become triglycerides), or (3) absorption into portal circulation (Grundy, 1987). The main target organs for the distribution and metabolism of lecithins are the intestinal wall and the liver (EFSA, 2017).

Fecal and urinary excretion of lecithin metabolites in humans has been reported to be minimal. Zierenberg and Grundy (1982) reported that less than 10% of the administered lecithin was recovered in feces collected over a 7-day period in five patients ingesting 1-gram capsules containing radiolabeled lecithin. They concluded that >90% of the lecithin was taken up by the intestines. Radiolabeled H_2O and water-soluble lecithin metabolites in urine accounted for >10% of the lecithin administered. In a high-dose study, Beil and Grundy (1980) reported negligible excretion of fatty acids in two volunteers receiving 30 g lecithin/day compared to excretion during a pre-dose period. In one volunteer

[2] EFSA (2017) reviews published and unpublished studies on the metabolic fate of radiolabeled phosphatidylcholine and the metabolism of lecithins into choline. Choline is rapidly absorbed and appears in plasma as free choline.

administered 75 g/day, only ~1 g fatty acid was excreted, leading the authors to conclude that the oral administration of high levels of lecithin did not adversely affect lipid absorption.

Acute Oral Toxicity

Studies of Lecithins

The evaluation by CIR (2001) included an acute oral toxicity data obtained from the US FDA via a Freedom of Information Act request. These included data from three unpublished studies that reported the acute oral LD_{50} of lecithin to be >16,000 mg/kg-bw for albino CD-1 mice and Wistar rats, and approximately 4,750 mg/kg-bw in Dutch-Belted rabbits (FDRL, 1973a,b,c, as reported in CIR, 2001).

Other Studies

Brownawell et al. (2011) reported the acute LD_{50} of AGPC as >10,000 mg/kg-bw in rats and mice and >3,000 mg/kg-bw in beagle dogs. While convulsions and respiratory depression were seen in some rats, only reduced activity was observed in dogs.

Heywood et al. (1987) reported the LD_{50} for a purified phospholipid preparation obtained from bovine cerebral cortex to be greater than 5,000 mg/kg-bw in rats.[3]

Honda and colleagues (2009) reported the acute oral LD_{50} of Asahi Kasei PI (purified phosphatidylinositol from soy lecithin) to be >2,000 mg/kg-bw in male and female Sprague-Dawley rats.

Repeated Oral Dose Toxicity

Lecithin Studies

Soy lecithin (no additional information on composition was provided) was used as a comparison in a 90-day rat study published by Gaunt et al. (1967) in which pathogen-free (SPF) rats (15/sex) received 6.0% soy lecithin in the diet daily for 13 weeks. No significant changes in hematology, renal function tests, organ weights, or gross necropsy were seen in treated animals compared to controls. The authors stated that the no-observed-adverse-effect level (NOAEL)[4] of soy lecithin was 6.0%, or 4,860 and 5,460 mg/kg-bw/day for males and females, respectively, as calculated by EFSA (2017).[5]

Other Studies

Several studies conducted by Brownawell et al. (2011) have been published. In the first study, no treatment-related effects were seen in Sprague-Dawley rats treated via gavage with AGPC at 0, 100, 300, or 1,000 mg/kg-bw/day for 28 days. In the second study, rats

[3] EFSA (2016) summarizes this study as reported in CIR (2015) but reports the test species to be mice.

[4] The authors used the term "minimum no-effect level."

[5] The study author calculated 6.0% to be equivalent to 3 g/kg/day.

were administered the same doses daily for 26 weeks. The authors of the study stated that exposure at the mid-dose (300 mg AGPC/kg-bw/day) in rats did not result in any toxic effects and identified a NOAEL of 300 mg AGPC/kg-bw/day.

Brownawell et al. (2011) also conducted similar studies in beagle dogs. In the first study, no treatment-related effects beyond reduced activity in the high-dose males were observed in dogs treated via gavage with AGPC in doses of 0, 75, 150, or 300 mg/kg-bw/day for 28 days. In a second study, dogs were administered the same doses daily for 26 weeks. The NOAEL for each study was identified as 150 mg/kg-bw/day based on changes in clinical chemistry associated with reduced liver function, and reduced organ weights (heart and liver).

Heywood et al. (1987) administered 0, 10, 100, or 1,000 mg/kg-bw/day purified phospholipid preparation obtained from bovine cerebral cortex via gavage to Sprague-Dawley rats for 26 weeks. While some clinical chemistry changes were noted, such as "slightly elevated" alkaline phosphatase or "slightly lowered" serum albumin levels at the highest dose, no significant treatment-associated effects were reported.

In the same publication discussed above, Honda et al. (2009) reported an oral subchronic toxicity study with Asahi Kasei purified phosphatidylinositol (PI). Using the Organisation for Economic Co-operation and Development (OECD) Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents), male and female Sprague- Dawley rats received 100, 300, or 1,000 mg Asahi Kasei PI /kg-bw/day for 13 weeks. No treatment-related changes were observed in body weight, food consumption, or ophthalmoscopy or urinalysis parameters. Low prothrombin times and reticulocyte ratios were observed in females of the highest dose group but were determined not to be biologically significant; no other hematological changes were noted. Changes in blood chemistry parameters were determined to be due to the desirable pharmacological effect of Asahi Kasei PI (reduced triglyceride and phospholipid levels) or not to be of biological significance (reduced albumin and protein levels). No deaths were reported, and no toxicologically significant changes were observed in gross necropsy, organ weights, or histopathology. The authors determined the oral NOAEL of Asahi Kasei PI to be the highest dose tested, 1,000 mg/kg-bw/day in male and female rats.

EFSA (2017) summarized the findings of several unpublished studies (dated 2013–2014) on essential phospholipid (EPL)[6] that were submitted:

- In the first study (Document provided to EFSA n.11), beagle dogs received 50, 250, or 2,500 mg EPL/mg-bw/day for six weeks via oral gavage (three per group), and six animals received solvent only (control group). Pharmacodynamic effects were seen on some biochemical markers of fat metabolism; no other treatment-related effects occurred in behavior, food/water

[6] EFSA (2017) noted that the compositio n of EPL was not always provided in study reports; however, when given, the composition was as follows: 65% linoleic acid, 5% linolenic acid, 10% oleic acid, 15% palmitic acid, and 5% stearic acid. The remaining 25% consisted of 5% phosphatidylethanolamine (kephalins) and 20% accompanying lipids from the soybean.

consumption, body-weight gain, hematology, urinalysis, or gross pathology. The authors determined the "lowest toxic dose" to be >2,500 mg/kg-bw/day.

- In the second study (Document provided to EFSA n.12), male and female Wistar rats (10/sex/group) were dosed via oral gavage with 0, 150, 750, or 3,750 mg/kg-bw/day of EPL for 12 weeks. No treatment-related effects were seen on behavior, body weight, food/water intake, hematology, urinalysis, or histopathology. The authors determined the "no-effect daily dose" to be >3,750 mg/kg-bw/day. The EFSA Panel identified the NOAEL to be 3,750 mg/kg-bw/day.
- In the third study (Document provided to EFSA n. 15), beagle dogs (three sex per group) received 0, 250, 500, or 1,000 mg EPL/kg-bw/day by capsule 5 days/week for one year. Six dogs served as control animals (no vehicle specified). A significant increase in triglyceride levels in females was seen with EPL exposure (no other details provided); no other significant treatment-related changes in hematology, urinalysis, pathology, or clinical observations were reported. The authors determined the "no-effect dose" to be >1,000 mg/kg-bw/day.
- In the fourth study (Document provided to EFSA n.13), Wistar rats (25/sex/group) were dosed orally with 0, 150, 750, or 3,750 mg/kg-bw/day for 24 weeks. No treatment-related effects were reported on behavior, body weight, food/water intake, hematology, urinalysis, organ weights, hearing, or vision. Observed macroscopic changes were determined not to be treatment-related. The NOAEL was determined[7] to be 3,750 mg/kg-bw/day.
- In the fifth study (Document provided to EFSA n.7), Wistar rats (25/sex/group) were dosed by oral gavage with 0, 150, 750, or 3,750 mg/kg-bw/day for 48weeks. No treatment-related effects were reported on behavior, body weight, food/water intake, hematology, urinalysis, organ weights, hearing, vision, or histopathology. The authors determined the "no-effect dosage" to be 3,750 mg/kg-bw/day; however, the EFSA Panel noted that the study had "some shortcomings" (no further details provided).

Reproductive and Developmental Toxicity

Lecithin Studies

No reproductive toxicity studies on lecithin were identified. However, teratology studies in three species conducted on lecithin were reviewed by CIR (2001[8]). These studies were not included in the 2015 CIR assessment, and the EFSA (2017) Panel noted a lack of details in the original study reports, including a lack of description of statistical methods. In each of these studies, pregnant dams were administered lecithin or corn oil by oral gavage during gestation and then underwent necropsy. Toxicological assessment included examination of

[7] It is not clear whether the authors and/or EFSA made this determination.

[8] Also cited as FDA (1974) in EFSA (2017).

implantation sites, resorption sites, and number of fetuses (live/dead). All fetuses were weighed and examined externally, then selected for detailed visceral or skeletal examinations.

- In Food and Drug Research Laboratories, Inc. (FDRL) (1973d, as cited in CIR, 2001), CD-1 mice (groups of 21 to 23) were dosed orally with 0, 16, 345, or 1,600 mg lecithin/kg-bw/day on gestation days 6–15 and sacrificed on day 17. No adverse effects were reported up to the highest dose tested.
- In FDRL (1973e, as cited in CIR, 2001), Wistar rats (groups of 22 to 24) were dosed orally with 16, 74.3, 345, or 1,600 mg lecithin/kg-bw/day on gestation days 6–15 and sacrificed on day 20. No adverse effects were reported up to the highest dose tested.
- In FDRL (1974, as cited in CIR, 2001), Dutch-Belted rabbits (groups of 10–12) were dosed orally with 4.75, 22.1, 100.3, or 475 mg lecithin/kg-bw/day on gestation days 6–18 and sacrificed on day 29. No adverse effects were reported up to the highest dose tested.

Based on the data from available studies, lecithin is not expected to be of concern for reproductive or developmental effects at the intended levels of use proposed herein.

The potential for lecithin to cause developmental neurotoxicity has been considered previously by regulatory agencies, including SCF (1997) and EFSA (2017), based on older studies in mice and rats (Gozzo et al., 1982; Bell and Lundberg, 1985; Bell and Slotkin, 1985; Bell et al.,1986). These studies were recently reviewed in detail by EFSA (2017, pp. 41–43), which noted the limitations in study design, including a lack of description of the number of pregnant animals, number of litters, sex of pups, length of gestation, and/or pup weight at birth and during tests. In addition, the EFSA Panel noted flaws in the study design of some of the neurodevelopmental tests conducted. However, while the relevance of these studies was determined to be limited, the Panel acknowledged the indications of possible behavioral effects and concluded that, "lecithins (E 322) use in infant formulae should not lead to choline intakes higher than the amount of total choline provided in human milk considered adequate by the NDA Panel."

Other Studies

Heywood et al. (1987) reported the findings of two reproductive and developmental toxicity studies. Purified phospholipid preparation obtained from bovine cerebral cortex did not produce treatment-related effects on litter size, post-implantation loss, fetal weights, or fetal development in rats. In this study, pregnant rats received 0, 10, 100, or 200 mg/kg-bw/day on gestations days 6–18. In a separate study following the same protocol, New Zealand white rabbits received the test material at 0, 50, 150, or 450 mg/kg-bw/day; no treatment-related effects were observed.

EFSA (2017) summarized the findings of two unpublished studies (dated 2013–2014) on essential phospholipid (EPL)[9] submitted in response to its call for data:

- In the first study (Document provided to EFSA n. 14), Wistar rats (groups of 24) were dosed orally with 100, 500, or 1,000 mg EPL/kg-bw/day on gestation days 6–15. No treatment-related effects were reported up to the highest dose tested on pathology, corpora lutea, implantations, litter size, fetal and placental weights, pre-/post-implantation loss, or external, visceral, or skeletal examination of fetuses. The authors determined the maternal and developmental NOAEL to be 1,000 mg/kg-bw/day (the highest dose tested); the EFSA (2017) Panel agreed with this NOAEL.
- In the second study (Document provided to EFSA n. 8), intravenous dosing of pregnant Wistar rats (groups of 24) did not result in any treatment-related effects on the same parameters evaluated, up to the highest dose of 10 mL/kg-bw/day. The EFSA (2017) Panel agreed with this NOAEL, noting the oral equivalent dose to be 1,000 mg/kg-bw/day.

Mutagenicity and Genotoxicity

Lecithin Studies

EFSA (2017) summarized the findings of an unpublished report from Litton Bionetics, Inc. (1975[10]), prepared for and submitted to FDA. In this study, lecithin (no other information provided) up to the highest concentration tested of 0.04% was shown not to be mutagenic with and without metabolic activation in an Ames test with *Salmonella typhimurium* strains TA1535, TA1537, and TA1538.

Other Studies

Brownawell et al. (2011) reported that AGPC was non-mutagenic in five strains of *S. typhimurium* with or without metabolic activation up to 10,000 µg/plate or *S. pombe* P1 up to 3,000 µg/mL. In addition, no changes in gene conversion frequency were observed in *S. cerevisiae* up to 10,000 µg/plate. *In vivo* assays reported in this same report also showed a lack of mutagenic potential of AGPC, including results of a mouse micronucleus assay up to 300 mg/kg-bw and a host-mediated gene conversion assay in rats up to 300 mg/kg-bw.

Heywood et al. (1987) summarized the results of three studies. No evidence of genotoxicity was observed in an *in vitro* chromosome aberration assay in human lymphocytes, a gene mutation assay in mouse lymphoma cells, an *in vitro* UDS (unscheduled DNA synthesis)

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[9] EFSA (2017) noted that the composition of EPL was not always provided in study reports; however, when given, the composition was as follows: 65% linoleic acid, 5% linolenic acid, 10% oleic acid, 15% palmitic acid, and 5% stearic acid. The remaining 25% consisted of 5% phosphatidylethanolamine (kephalins) and 20% accompanying lipids from the soybean.

[10] This study report was prepared for and submitted to FDA in 1975. It is assumed that EFSA obtained this study via direct interaction with FDA.

assay in HELA S3 cells, and an *in vivo* oral micronucleus assay in mice (up to 300 mg/kg-bw).

Kato et al. (2009) stated that hydrogenated lecithin (Lpsm-Flln or Lpsm) up to 5,000 µg/plate was not genotoxic in four strains of *S. typhimurium* or *Escherichia coli* strain WP2uvrA, with or without metabolic activation.

Asahi Kasei PI was demonstrated to lack mutagenic and genotoxic potential in the conditions of the respective test assays (Honda et al., 2009).

- Testing according to OECD Guideline 471 (Bacterial Reverse Mutation Test) was performed at concentrations of 315–5,000 µg/plate (based on the results of preliminary tests) with *S. typhimurium* strains TA1535 and TA100[11] and *Escherichia coli* WP2 *uvrA*. Asahi Kasei PI was negative for mutagenic activity up to the highest concentration tested with and without metabolic activation.
- Testing according to OECD Guideline 473 (*In Vitro*, Mammalian Chromosome Aberration Test) was performed at concentrations of 1,250, 2,500, or 5,000 µg/mL (based on a lack of cell growth inhibition in preliminary tests[12]) in a Chinese hamster cell line, CHL/IU. Asahi Kasei PI was negative for ability to induce structural chromosome aberrations and numerical chromosome aberrations up to the highest concentration tested with and without metabolic activation.

EFSA (2017) summarized the findings of several unpublished studies on ESSENTIALE 303™, a multivitamin preparation containing lecithin (50 mg/mL). ESSENTIALE 303™ was shown to be non-mutagenic and nongenotoxic in a total of five studies, which were submitted in response to a call for data (cited in EFSA, 2017) as document provided to EFSA n.10; conducted in 2013).

Carcinogenicity

In a study by Brantom et al. (1973), Wistar rats received 4% dietary soy lecithin for two years, correlating to 1,470 and 2,280 mg/kg-bw/day for males and females, respectively. Control animals were administered a commercial diet. Increased parathyroid gland hyperplasia was observed (more so in males), which was attributed by the authors to an increased phosphate intake. No difference in tumor incidence was seen between treated and control animals. A "no-untoward effect level" of 4% in the diet, equivalent to 1,470 and 2,280 mg/kg-bw/day for males and females, respectively, was identified by the study authors. The EFSA (2017) Panel agreed with this conclusion.

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[11] EFSA (2017) reports strains TA1538 and not TA98; however, these strains are reported here as described in the published manuscript.

[12] The high dose used in this study is 2.5x the recommended dose in the OECD guideline. For this reason, the EFSA (2017) Panel "noted that the study was performed essentially in agreement with the current OECD Guideline no. 473."

Human Studies

Several oral and intravenous studies of phosphatidylserine conducted in humans were reviewed in GRN 545 (pp. 23–28), GRN 186 (pp. 14–16), and CIR (2015, p. 10). GRN 545 (pp. 23–24) reported on the availability of over 42 clinical trials, in which 1,600 subjects received 100–800 mg/day phosphatidylserine for periods of up to 6 months and concluded that doses of up to 600 mg/day for three months were without significant adverse effects.

A recently published randomized, placebo-controlled, double-blind clinical trial conducted on a phosphatidylserine and phosphatidic acid complex, phosphatidic acid complex (PAS) was identified (Schmidt et al., 2018). In this limited study, four women (18–45 years) received either a placebo or PAS (400 mg each phosphatidylserine and phosphatidic acid) daily for the duration of three menstrual cycles. No treatment-related effects were observed on the salivary or serum hormone levels measured, with the exception of cortisol in some cycles. The authors determined the daily intake of PAS to be "safe."

Safety Data Summary

Based on the biochemistry and fate of lecithins in the human body, lecithin from an alternative source (i.e., sunflower oil) would not be expected to have toxicokinetic properties different from another, plant-derived lecithin that has already been determined to be GRAS for human consumption. The existing information described above addresses all toxicological endpoints that are relevant to the human oral consumption of lecithin (e.g., absorption, distribution, metabolism, and excretion [ADME], acute and repeated-dose oral toxicity, reproductive and developmental toxicity, genotoxicity, mutagenicity, carcinogenicity). In addition, the constituents of sunflower lecithin are commonly consumed as part of a normal human diet. "In humans, dietary lecithins are known to be hydrolyzed and liberate choline, an essential nutrient and precursor to the neurotransmitter, acetylcholine. Adequate Intakes and Upper Tolerable Limits have been established by the Food and Nutrition Board of the National Institute of Medicine. The tolerable upper intake level (UL) for choline for children 1-8 years is 1000 mg/day; for children 9-13 years is 2000 mg/day, for adolescents 14-18 years, 3000 mg/day and adults 19 years and older, 3500 mg/day; a UL was not established for infants 0-12 months of age. The potential choline intake resulting from lecithins in food are well below the upper intake levels (UL) for choline (EFSA, 2017)".

The totality of information available on lecithin and related compounds that have been reviewed as part of this current GRAS assessment is considered to be sufficient to support the safe use of lecithin derived from sunflower oil for the proposed intended uses described herein.

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 Act (FFDCA) (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 sunflower lecithin in food for human consumption is GRAS based on scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FFDCA.

Safety Determination

Lecithins from numerous plant sources, as well as sunflower lecithin, are currently marketed for use in food for human consumption, including non-exempt infant formula. The proposed sunflower lecithin has a phospholipid and fatty-acid profile similar to that of currently approved/marketed lecithin products from other plant sources. Sunflower oil is proposed as an alternative source of lecithin, and the sunflower lecithin that is the subject of the GRAS determination would be added to food in a manner similar to lecithins derived from the oil sources cited in 21 CFR § 184.1400.

The identity of the Sternchemie sunflower-derived lecithin is similar to the product considered GRAS in GRN 533 (FDA, 2015a) and GRN 682 (FDA, 2017), which received no questions from FDA, and is proposed for the same intended uses therein. Additionally, lecithin also comprises hydrolyzed products through the use of appropriate enzymes and enzyme-modified lecithin is also GRAS according to 21 CFR § 184.1063.

Additional sources for or derivatives of lecithin that have been notified as GRAS to FDA with "no questions" letters issued include krill-based (GRN 226; FDA, 2008), soy lecithin phosphatidylserine complex (GRN 186; FDA, 2006b and GRN 197; FDA, 2006c), fish

phosphatidylserine from lecithin from fish biomass (GRN 279; FDA, 2009), phosphatidylserine from krill lecithin (GRN 311; FDA, 2010), phosphatidylserine derived from sunflower lecithin or soy lecithin (GRN 545; FDA, 2015b), and soybean-derived hydrogenated lecithin (GRN 534; FDA, 2014).

Based on the known biochemistry and fate of lecithins in the human body, it is not expected that lecithin derived from an alternative source such as sunflower oil would have toxicokinetic properties different from other plant-derived lecithins that have already been determined to be GRAS for human consumption. The safety reviews described above—documented in the CFR, and by SCOGS, SCF, GRN Panels, CIR, and EFSA—each involved a panel of qualified experts charged with reaching a conclusion regarding the safe use of a lecithin-related product in a variety of specified foods. These evaluations covered all toxicological endpoints relevant to human oral consumption of lecithin (e.g., ADME, acute- and repeated-dose oral toxicity, reproductive and developmental toxicity, genotoxicity, mutagenicity, carcinogenicity, and sensitization/ allergenicity). Regulatory authorities have independently reviewed the composition and safety study database for various plant-derived lecithin products, including sunflower lecithin, and found no issues of concern with respect to their use in human food, including non-exempt infant formula. Therefore, it can be considered that the totality of information available on lecithin and related compounds is sufficient to support the safe use of the proposed lecithin products derived from sunflower oil for the intended uses herein.

General Recognition of the Safety of Sunflower Lecithin

The intended use of sunflower lecithin has been determined to be safe through the scientific procedures 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 lecithin products that are the subject of this notification are a mixture of acetone-insoluble phosphatides that consists mainly of phosphatidylcholine, phosphatidylinositol, phosphatidylethanolamine, and phosphatidic acid, as well as diverse amounts of other substances such as triglycerides, fatty acids, and carbohydrates derived from sunflower. The sunflower lecithin products are manufactured consistent with cGMP for food (21 CFR § 110 and § 117 Subpart B). The raw materials and processing aids used in the manufacturing process are all food grade and approved for use as in food.
- The long history of lecithin consumption by humans is common knowledge. Numerous food products containing sunflower-derived lecithin and/or lecithin derived from other plant sources are marketed in the United States and around the world, and lecithin has become a desirable ingredient for addition to a variety of food products as a nutritional ingredient, and as an emulsifier, wetting or instantizing agent, viscosity modifier, releasing agent, extrusion aid, low-flavor binding material, and high-quality dietary fat source.
- Lecithin is approved for use in food in 21 CFR § 184.1400, and it can be used in food with no limitation other than cGMP. Sternchemie's sunflower lecithin is intended for use as a source of lecithin that is an alternative to lecithins

derived from other plant sources such as soy, corn, and sunflower currently in the marketplace. Numerous lecithin ingredients from other plant or grain sources are recognized as GRAS for their intended uses in foods, including lecithin from canola, lecithin from krill, hydrogenated lecithin from soy, phosphatidylserine derived from soy lecithin, soy lecithin enzymatically modified to contain increased phosphatidylserine, and soy protein hydrolysate with enzyme-modified lecithin.

- Based on the biochemistry and fate of lecithins in the human body, it is not expected that lecithin derived from an alternative source such as sunflower oil would have toxicokinetic properties different from other, plant-derived lecithins already determined to be GRAS for human consumption. Safety reviews by SCOGS, SCF, GRNs, CIR, and EFSA each involved a panel of qualified experts charged with reaching a conclusion regarding the safe use of a lecithin-related product for human use. The evaluations covered all toxicological endpoints that are relevant to human oral consumption of lecithin (e.g., ADME, acute and repeated-dose oral toxicity, reproductive and developmental toxicity, genotoxicity, mutagenicity, carcinogenicity, and sensitization/allergenicity).
- Regulatory authorities have reviewed the composition and safety study database for various plant-derived lecithin products, including sunflower lecithin, and found no issues of concern with respect to their use in human food, including non-exempt infant formula.
- Therefore, the publicly available scientific literature on the consumption and safety of sunflower lecithin and lecithin ingredients is sufficient and supports the safety and GRAS status of the proposed sunflower lecithin product.

Because 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 sunflower lecithin that is the subject of this self-determination has been made through the deliberations of a GRAS Panel of experts convened by Sternchemie and comprised of Michael Carakostas, DVM, Ph.D., Stanley M. Tarka, Jr., Ph.D., F.A.T.S., and Thomas Vollmuth, Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that sunflower lecithin, produced in a manner consistent with cGMP and meeting the specifications described herein, is safe under its intended conditions of use.

The Panel further unanimously concluded that these uses of sunflower lecithin 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. The Panel's GRAS opinion is included in this document as Exhibit 1.

It is also Sternchemie's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion.

Sternchemie has concluded that sunflower lecithin is GRAS under the intended conditions of use, on the basis of scientific procedures; therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the United States without the promulgation of a food additive regulation under Title 21 of the CFR.

Sternchemie is not aware of any information that would be inconsistent with a finding that the proposed use of sunflower lecithin in food for human consumption that meets appropriate specifications, and used according to cGMP, is GRAS. Recent reviews of the scientific literature have not revealed any potential adverse health concerns.

§ 170.250 Part 7, Supporting Data and Information

The following references are all generally available, unless otherwise noted. Appendix A, Appendix B, and Exhibit 1 (analytical COAs and stability testing data for sunflower lecithin and signed GRAS Panel report) are not generally available but are attached for reference.

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APPENDIX A

Certificates of Analysis

Certificate of Analysis

Sunflower Lecithin
LeciStar S 100

Batch-No.:PSC019269 **Our reference: Tank 16**

Manufacturing Date: 02/2018 **BBD: 08/2019**

Parameter	Specification	Result	Unit
Acetone insolubles	≥ 60	62.72	%
Water	≤ 0.8	0.52	%
Toluene-insoluble matter	≤ 0.3	0.24	%
Peroxide value	≤ 5	0.0	meq/kg
Colour (Gardner, 10%)	≤ 12	12	
Acid Value	≤ 30	27.04	mgKOH/g
Aerobe mesophile total plate count	≤ 3000	<10	cfu/g
Yeasts	≤ 100	<10	cfu/g
Moulds	≤ 100	<10	cfu/g
E. coli	negative	negative	in 1 g
Salmonella	negative	negative	in 25 g

No GMO labeling required according to Regulations (EC) No 1829/2003 and 1830/2003. Respective analysis has been carried out on a representative sample of the product by an independent laboratory with EN ISO/EC 17025 accreditation by hexa screening (35S, NOS, transEPSPS, synPAT, bar-Gen, SAMS-HRA) prior to dispatch of the product.

Date: 26.02.2018

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Certificate of Analysis

Sunflower Lecithin
LeciStar S 100

Batch-No.:PSC021915_AOSC21724 **Our reference: Tank 17**

Manufacturing Date: 08/2019 **BBD: 02/2021**

Parameter	Specification	Result	Unit
Acetone insolubles	≥ 60	67.87	%
Water	≤ 0.8	0.5	%
Toluene-insoluble matter	≤ 0.3	0.23	%
Peroxide value	≤ 5	0	meq/kg
Colour (Gardner, 10%)	≤ 12	11.5	
Acid Value	≤ 30	25.27	mgKOH/g
Aerobe mesophile total plate count	≤ 3000	<10	cfu/g
Yeasts	≤ 100	<10	cfu/g
Moulds	≤ 100	<10	cfu/g
E. coli	negative	negative	in 1 g
Salmonella	negative	negative	in 25 g

No GMO labeling required according to Regulations (EC) No 1829/2003 and 1830/2003. Respective analysis has been carried out on a representative sample of the product by an independent laboratory with EN ISO/EC 17025 accreditation by hexa screening (35S, NOS, transEPSPS, synPAT, bar-Gen, SAMS-HRA) prior to dispatch of the product.

Date: 26.08.2019

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Certificate of Analysis

Sunflower Lecithin
LeciStar S 100

Batch-No.:PSC01669 **Our reference: Tank 16**

Manufacturing Date: 07/2019 **BBD: 01/2021**

Parameter	Specification	Result	Unit
Acetone insolubles	≥ 60	63.39	%
Water	≤ 0.8	0.28	%
Toluene-insoluble matter	≤ 0.3	0.17	%
Peroxide value	≤ 5	0.59	meq/kg
Colour (Gardner, 10%)	≤ 12	12	
Acid Value	≤ 30	26.91	mgKOH/g
Aerobe mesophile total plate count	≤ 3000	<10	cfu/g
Yeasts	≤ 100	<10	cfu/g
Moulds	≤ 100	<10	cfu/g
E. coli	negative	negative	in 1 g
Salmonella	negative	negative	in 25 g

No GMO labeling required according to Regulations (EC) No 1829/2003 and 1830/2003. Respective analysis has been carried out on a representative sample of the product by an independent laboratory with EN ISO/EC 17025 accreditation by hexa screening (35S, NOS, transEPSPS, synPAT, bar-Gen, SAMS-HRA) prior to dispatch of the product.

Date: 16.08.2019

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Certificate of Analysis

De-oiled Sunflower Lecithin
SternPur SP

Batch-No.:PSC017108 **Our reference:**

Manufacturing Date: 12/2016 **BBD: 12/2018**

Parameter	Specification	Result	Unit
Acetone insolubles	≥ 96	96.8	%
Water	≤ 1.5	1.26	%
Peroxide value	≤ 5	0.2	meq/kg
Acid Value	≤ 35	30.6	mgKOH/g
Aerobe mesophile total plate count	≤ 3000	60	cfu/g
Yeasts	≤ 100	<10	cfu/g
Moulds	≤ 100	10	cfu/g
E. coli	negative	negative	in 1 g
Salmonella	negative	negative	in 25 g

No GMO labeling required according to Regulations (EC) No 1829/2003 and 1830/2003. Respective analysis has been carried out on a representative sample of the product by an independent laboratory with EN ISO/EC 17025 accreditation by hexa screening (35S, NOS, transEPSPS, synPAT, bar-Gen, SAMS-HRA) prior to dispatch of the product.

Date: 11.01.2017

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Certificate of Analysis

De-oiled Sunflower Lecithin
SternPur SP

Batch-No.:PSC019616 **Our reference:**

Manufacturing Date: 05/2018 **BBD: 05/2020**

Parameter	Specification	Result	Unit
Acetone insolubles	≥ 96	98.1	%
Water	≤ 1.5	1.12	%
Peroxide value	≤ 5	0.9	meq/kg
Acid Value	≤ 35	29.6	mgKOH/g
Aerobe mesophile total plate count	≤ 3000	650	cfu/g
Yeasts	≤ 100	30	cfu/g
Moulds	≤ 100	50	cfu/g
E. coli	negative	negative	in 1 g
Salmonella	negative	negative	in 25 g

No GMO labeling required according to Regulations (EC) No 1829/2003 and 1830/2003. Respective analysis has been carried out on a representative sample of the product by an independent laboratory with EN ISO/EC 17025 accreditation by hexa screening (35S, NOS, transEPSPS, synPAT, bar-Gen, SAMS-HRA) prior to dispatch of the product.

Date: 22.05.2018

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Certificate of Analysis

De-oiled Sunflower Lecithin
SternPur SP

Batch-No.:PSC021836 **Our reference:**

Manufacturing Date: 07/2019 **BBD: 07/2021**

Parameter	Specification	Result	Unit
Acetone insolubles	≥ 96	97.3	%
Water	≤ 1.5	1.09	%
Peroxide value	≤ 5	0	meq/kg
Acid Value	≤ 35	31.2	mgKOH/g
Aerobe mesophile total plate count	≤ 3000	150	cfu/g
Yeasts	≤ 100	<10	cfu/g
Moulds	≤ 100	<10	cfu/g
E. coli	negative	negative	in 1 g
Salmonella	negative	negative	in 25 g

No GMO labeling required according to Regulations (EC) No 1829/2003 and 1830/2003. Respective analysis has been carried out on a representative sample of the product by an independent laboratory with EN ISO/EC 17025 accreditation by hexa screening (35S, NOS, transEPSPS, synPAT, bar-Gen, SAMS-HRA) prior to dispatch of the product.

Date: 24.07.2018

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Sternchemie
Liquid Technology

Certificate of Analysis

SternPhil S DH 50

Batch-No.: PSC019451 **Our reference:**

Customers reference / additional data:

Delivery date:

Quantity: **Packaging: 200 kg drums**

Manufacturing Date: 03/2018 **BBD: 09/2019**

Parameter	Specification	Result value	Unit
Acetone insolubles	≥ 56	56,23	%
Water	≤ 1	0,33	%
Toluene-insoluble matter	≤ 0.3	0,15	%
Peroxide value	≤ 5	0,4	meq/kg
Colour (Gardner, 10%)	≤ 13	11,75	
Acid value	≤ 45	37,60	mgKOH/g
Viscosity (25°C)	≤ 12000	6.840	mPa*s
Degree of hydrolysis	43-54	46,01	mol-%
Aerobic mesophile micro-organisms	≤ 3000	< 10	CFU/g
Yeast	≤ 100	< 10	CFU/g
Mould	≤ 100	< 10	CFU/g
E. coli	negative	Negative	in 1 g
Salmonella	negative	Negative	in 25 g

PCR certificate issued by independent laboratory Impetus, Bremerhaven: PIB18-01636

No GMO labeling required according to EU regulation 1829/2003 and 1830/2003. Respective analysis will be carried out by an independent laboratory with EN ISO/EC 17025 certification prior to dispatch of the product. Analysis is carried out by screening for soy and rapeseed DNA and for the specific GMO events 35 S and NOS (50 cycles) with a detection limit of max. 0.9%.

Analytical values can only be guaranteed within the scope of performed methods used by Sternchemie GmbH & Co.KG. Reference methods of determination will be indicated on request. Analytical results refer to the analysed sample and do not necessarily represent the whole product it was taken from. Further, we cannot guarantee the suitability for special applications on customer's side. The consignee is responsible for checking the given information on receipt of goods.

Date / Signature: 16.04.2018

i. A. '

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Sternchemie
Lipid technology

Certificate of Analysis

SternPhil S DH 50

Batch-No.: PSC020071 **Our reference:**

Customers reference / additional data:

Delivery date:

Quantity: **Packaging: 200 kg drums**

Manufacturing Date: 08/2018 **BBD: 01/2020**

Parameter	Specification	Result value	Unit
Acetone insolubles	≥ 56	57,06	%
Water	≤ 1	0,37	%
Toluene-insoluble matter	≤ 0.3	0,09	%
Peroxide value	≤ 5	0	meq/kg
Colour (Gardner, 10%)	≤ 13	12,5	
Acid value	≤ 45	40,54	mgKOH/g
Viscosity (25℃)	≤ 12000	8.940	mPa*s
Degree of hydrolysis	43-54	45,8	mol-%
Aerobic mesophile micro-organisms	≤ 3000	<10	CFU/g
Yeast	≤ 100	<10	CFU/g
Mould	≤ 100	<10	CFU/g
E. coli	negative	negative	in 1 g
Salmonella	negative	negative	in 25 g

PCR certificate issued by independent laboratory Impetus, Bremerhaven: PIB18-04656

No GMO labeling required according to EU regulation 1829/2003 and 1830/2003. Respective analysis will be carried out by an independent laboratory with EN ISO/EC 17025 certification prior to dispatch of the product. Analysis is carried out by screening for soy and rapeseed DNA and for the specific GMO events 35 S and NOS (50 cycles) with a detection limit of max. 0.9%.

Analytical values can only be guaranteed within the scope of performed methods used by Sternchemie GmbH & Co.KG. Reference methods of determination will be indicated on request. Analytical results refer to the analysed sample and do not necessarily represent the whole product it was taken from. Further, we cannot guarantee the suitability for special applications on customer´s side. The consignee is responsible for checking the given information on receipt of goods.

Date / Signature: 06.12.18 /

Sternchemie GmbH + Co. KG

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www.sternchemie.de

Sternchemie
Lipid Technology

Certificate of Analysis

SternPhil S DH 50

Batch-No.: PSC022227 **Our reference:**

Customers reference / additional data:

Delivery date:

Quantity: **Packaging: 200 kg drums**

Manufacturing Date: 10/2019 **BBD: 04/2021**

Parameter	Specification	Result	Unit
Acetone insolubles	≥ 56	56,64	%
Water	≤ 1	0,42	%
Toluene-insoluble matter	≤ 0.3	0,10	%
Peroxide value	≤ 5	0,0	meq/kg
Colour (Gardner, 10%)	≤ 13	12,0	
Acid Value	≤ 45	41,37	mgKOH/g
Viscosity (25°C)	≤ 12000	7.020	mPa·s
Degree of hydrolysis	43-54	47,65	mol-%
Aerobe mesophile total plate count	≤ 3000	< 10	cfu/g
Yeasts	≤ 100	< 10	cfu/g
Moulds	≤ 100	< 10	cfu/g
E. coli	Negative	Negative	in 1 g
Salmonella	Negative	Negative	in 25 g

No GMO labeling required according to Regulations (EC) No 1829/2003 and 1830/2003. Respective analysis has been carried out on a representative sample of the lecithin raw material by an independent laboratory with EN ISO/EC 17025 accreditation by hexa screening (35S, NOS, transEPSPS, synPAT, bar-Gen, SAMS-HRA) prior to dispatch of the product.

Analytical values can only be guaranteed within the scope of performed methods used by Sternchemie GmbH & Co.KG. Reference methods of determination will be indicated on request. Analytical results refer to the analysed sample. Further, we cannot guarantee the suitability for special applications on customer's side. The consignee is responsible for checking the given information on receipt of goods.

Date: 16.10.2019

Signature:

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STERN

NOFALAB
Laboratories

SternChemie GmbH & Co KG
An der Alster 81

20099 Hamburg
Germany

Certificate of Analysis

No. 2019043828

Date: 27-8-2019

Instruction received on	21-8-2019
Sample received	21-8-2019
Product	Sunflower lecithin
Packing	1 Plastic bottle
Sample quantity	1 l
Sample temperature	Ambient
Sample sealed	No
Markings	
Sample description	Sunflower lecithin AOSC21724_

Test Results:

2019043828.00

Package

Dioxins

WHO PCDD/F-TEQ excl. LOQ 2005	0,009 pg/g fat
WHO PCDD/F-TEQ incl. LOQ 2005	0,162 pg/g fat
WHO PCDD/F + DL-PCBs TEQ excl. LOQ 2005	0,017 pg/g fat
WHO PCDD/F + DL-PCBs TEQ incl. LOQ 2005	0,282 pg/g fat
Polychlorinated dibenzodioxins	
2,3,7,8-TCDD (1746-01-6)	Less than 0,050 pg/g fat
1,2,3,7,8-PeCDD (40321-76-4)	Less than 0,050 pg/g fat
1,2,3,4,7,8-HxCDD (39227-28-6)	Less than 0,050 pg/g fat
1,2,3,6,7,8-HxCDD (57653-85-7)	Less than 0,050 pg/g fat
1,2,3,7,8,9-HxCDD (19408-74-3)	Less than 0,050 pg/g fat
1,2,3,4,6,7,8-HpCDD (35822-46-9)	Less than 0,050 pg/g fat
OCDD (3268-87-9)	Less than 0,200 pg/g fat
Polychlorinated dibenzofurans	
2,3,7,8-TCDF (51207-31-9)	0,090 pg/g fat
1,2,3,7,8-PeCDF (57117-41-6)	Less than 0,050 pg/g fat

: accredited method (accreditation number L440)

All reported results are approved by the responsible labmanager.
The results of the examination refer exclusively to the checked samples. Duplicates of this certificate must be authorized by Nofalab in written form. Additional information concerning the perfomance characteristics of this analysis such as measurement uncertainty is available upon request. All our services are subjected to general conditions applicable as deposited at Chamber of Commerce of Rotterdam, KVK-no. 24361065.

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Results reported are expressed in product unless clearly stated otherwise.

2,3,4,7,8-PeCDF (57117-31-4)	Less than 0,050 pg/g fat
1,2,3,4,7,8-HxCDF (70648-26-9)	Less than 0,050 pg/g fat
1,2,3,6,7,8-HxCDF (57117-44-9)	Less than 0,050 pg/g fat
2,3,4,6,7,8-HxCDF (60851-34-5)	Less than 0,050 pg/g fat
1,2,3,7,8,9-HxCDF (72918-21-9)	Less than 0,050 pg/g fat
1,2,3,4,6,7,8-HpCDF (67562-39-4)	Less than 0,050 pg/g fat
1,2,3,4,7,8,9-HpCDF (55673-89-7)	Less than 0,050 pg/g fat
OCDF (39001-02-0)	Less than 0,200 pg/g fat

Dioxin like PCB's

PCB 77 (80333-65-9)	3,320 pg/g fat
PCB 81 (70362-50-4)	Less than 2,000 pg/g fat
PCB 126 (57465-28-8)	Less than 0,500 pg/g fat
PCB 169 (56-25-7)	Less than 2,000 pg/g fat
PCB 105 (35899-54-8)	69,410 pg/g fat
PCB 114 (74472-37-0)	Less than 10,000 pg/g fat
PCB 118 (31508-00-6)	155,000 pg/g fat
PCB 123 (65510-44-3)	Less than 10,000 pg/g fat
PCB 156 (38380-08-4)	19,450 pg/g fat
PCB 157 (69782-90-7)	Less than 10,000 pg/g fat
PCB 167 (52663-72-6)	Less than 10,000 pg/g fat
PCB 189 (39635-31-9)	Less than 10,000 pg/g fat
WHO-PCB-TEQ (WHO 2005) excl. LOQ	0,008 pg/g fat
WHO-PCB-TEQ (WHO 2005) incl. LOQ	0,120 pg/g fat

Non dioxine like PCB's

PCB 28 (7012-37-5)	Less than 0,100 ng/g fat
PCB 52 (35693-99-3)	Less than 0,100 ng/g fat
PCB 101 (37680-73-2)	0,130 ng/g fat
PCB 138 (35065-28-2)	0,110 ng/g fat
PCB 153 (8020-83-5)	Less than 0,100 ng/g fat
PCB 180 (35065-29-3)	Less than 0,100 ng/g fat
PCB SUM (PCB 28, 52, 101, 138, 153, 180) incl.LOQ	0,640 ng/g fat

Metals

Arsenic (As) (7440-38-2)	0,01 mg/kg
Cadmium (Cd) (7440-43-9)	Less than 0,01 mg/kg
Lead (Pb) (7439-92-1)	Less than 0,01 mg/kg
Mercury (Hg) (7439-97-6)	0,02 mg/kg

Mycotoxin

Ochratoxin A (303-47-9)	4,6 µg/kg

accredited method (accreditation number L440)

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Laboratories

Certificate No. **2019043828**
Date: 27-8-2019

Pesticides

Pesticide Package 1: Pesticides Flexible scope Organic analyses (multiresidue methode GC-MS/MS, LC-MS/MS positive mode) NL/10a/b/c (in accordance with EN 15662). **Acc. to the Nofalab pesticides list version: 01-01-2019**	Not detected

Pesticides (Components analysed and reported upon customer request, out of package 06),
(Ionic Pesticides analyses individual parameters) NL/10d in accordance with QUPPE SRM method.
Acc. to the Nofalab pesticides list version: 01-01-2019

Glycine derivative

Glyphosate (1071-83-6)	Less than 0,015 mg/kg

Polycyclic Aromatic Hydrocarbons

PAH's, (Polycyclic Aromatic Hydrocarbons)

Benzo(a)anthracene (56-55-3)	4,0 µg/kg
Chrysene (218-01-9)	4,8 µg/kg
Benzo(b)fluoranthene (205-99-2)	4,7 µg/kg
Benzo(a)pyrene (50-32-8)	4,3 µg/kg
Sum of PAH-4	17,9 µg/kg
Notification;	Analysis performed on fat content

: accredited method (accreditation number L440)

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Certificate No. **2019043828**
Date: 27-8-2019

ANNEX

Sample Determination

Method	**EN 15662**
Analysis	Pesticides Package 01
Norm	In accordance with EN 15662
WI	NL/10a/b/c
Device	LC-MS/MS and GC-MS/MS
Method	**Dioxins & Dioxin-like PCB's**
Analysis	Dioxin like PCB's,Dioxins
Norm	In accordance with Directive (EU) nr. 2017/644 (for Food)
WI	NL/22b
Device	GC-HR/MS
Method	**Determination of metals**
Analysis	Arsenic (As),Mercury (Hg),Cadmium (Cd),Lead (Pb)
Norm	In-house method
WI	NL/27
Device	ICP-MS
Method	**Determination of the content of PolycyclicAromaticHydrocarbons (PAH's)**
Analysis	PAH's, (Polycyclic Aromatic Hydrocarbons)
Norm	In accordance with ISO 22959
WI	NL/03
Device	DACC-HPLC Fluorescence
Method	**QuPPe and QuPPe- AO**
Analysis	Pesticides Package 06 (Components requested)
Norm	In accordance with QuPPe and QuPPe-AO
WI	NL/10d
Device	LC-MS/MS
Method	**Determination of the content of mycotoxins**
Analysis	Ochratoxin A
Norm	In-house method
WI	NL/13
Device	LC-MS/MS
Method	**Non dioxin-like PCB's**
Analysis	Non dioxine like PCB's
Norm	In-house method
WI	NL/22b
Device	GC-HR/MS

Sample preparation

Method	**Dioxins sample preparation (Food)**
Norm	In-house method
WI	NL/22a

Method	**Dioxins sample preparation (Food)**
Norm	In-house method
WI	NL/22a

accredited method (accreditation number L440)

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Laboratories

Certificate No. **2019043828**
Date: 27-8-2019

ANNEX

Sample Determination

Method	**Determination of the content of PolycyclicAromaticHydrocarbons (PAH's) in extracted fat**
Analysis	PAH's, (Polycyclic Aromatic Hydrocarbons)
Norm	In accordance with ISO 22959
WI	NL/03

Sample preparation

Nofalab B.V.
M. Bruggeman
Director

: accredited method (accreditation number L440)

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NofaLab laboratories

SternChemie GmbH & Co KG
An der Alster 81
20099 Hamburg
Germany

Certificate of Analysis No. 201808571

Date : 6-3-2018

Instruction received on	:	26-02-2018
Sample received	:	26-02-2018
Sample said to be	:	Lecithin
Packing	:	Plastic Bottle (clear)
Sample quantity	:	1,00 l
Sample temperature	:	Ambient
Sample sealed	:	Yes - lid seal
Marked	:	LeciStar S100, PSC 019269 Tank: 16

Test Results:

Approved by: JM

Polycyclic Aromatic Hydrocarbons: DACC-HPLC fluorescence, in accordance with ISO 22959, NL/03

Benzo(a)pyrene	2,6 µg/kg
Benzo(a)anthracene	6,4 µg/kg
Benzo(b)fluoranthene	2,5 µg/kg
Chrysene	6,4 µg/kg
Sum of PAH-4	17,9 µg/kg
Results of analysis performed in fat,	.

Mycotoxins

Approved by: JM

Aflatoxin (LC-MS/MS, in-house method, NL/13)

Aflatoxin B1	less than 0,5 µg/kg
Aflatoxin Total B1, B2, G1 and G2	less than 2,0 µg/kg

Approved by: JM

Ochratoxin (LC-MS/MS, in-house method, NL/13)

Ochratoxin A	4,9 µg/kg

: accredited method (accreditation number L440)

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Certificate No. **201808571**
Date : 06-03-2018

Metal and Element analysis

Approved by: SdR

Arsenic

Arsenic (As) (ICP-MS, in-house method NL/27)	0,02 mg/kg

Approved by: SdR

Cadmium

Cadmium (Cd) (ICP-MS, in-house method NL/27)	0,02 mg/kg

Approved by: SdR

Mercury

Mercury (Hg) (ICP-MS, in-house method NL/27)	less than 0,01 mg/kg

Approved by: SdR

Lead

Lead (Pb) (ICP-MS, in-house method NL/27)	less than 0,01 mg/kg

Approved by: SdR

Heavy metals as Pb

Heavy metals (as Pb) (USP 231)	less than 10 mg/kg

Approved by: JM

Pesticides Flexible scope Organic analyses (multiresidue methode GC-MS/MS, LC-MS/MS positive mode) NL/10a/b/c (in accordance with EN 15662). Acc. to the Nofalab pesticides list version: 01-01-2018.

Pesticides (Multi Method, BBFP1)	Not Detected

Approved by: JM

Ionic Pesticides analyses individual parameters NL/10d (in accordance with QUPPE SRM method). Acc. to the Nofalab pesticides list version: 01-01-2018

Pesticides (Single Residue Method, Ion, BBFP6)	Not Detected

Approved by: FH

Dioxins (GC-HR/MS, in-house method NL/22a/b, NEN-EN 16215 (feed), Regulation EU2017/771 (feed) & EU 2017/664 (food))

Polychlorinated dibenzodioxins	.
2,3,7,8-TCDD	less than 0,05 ng/kg
1,2,3,7,8-PeCDD	less than 0,05 ng/kg
1,2,3,4,7,8-HxCDD	less than 0,05 ng/kg
1,2,3,6,7,8-HxCDD	less than 0,05 ng/kg
1,2,3,7,8,9-HxCDD	less than 0,05 ng/kg
1,2,3,4,6,7,8-HpCDD	less than 0,05 ng/kg
OCDD	0,31 ng/kg
Polychlorinated dibenzofurans	.
2,3,7,8-TCDF	less than 0,05 ng/kg
1,2,3,7,8-PeCDF	less than 0,05 ng/kg

: accredited method (accreditation number L440)

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Date : 06-03-2018

Approved by: FH

Dioxins (GC-HR/MS, in-house method NL/22a/b, NEN-EN 16215 (feed), Regulation EU2017/771 (feed) & EU 2017/664 (food))

2,3,4,7,8-PeCDF	less than 0,05 ng/kg
1,2,3,4,7,8-HxCDF	less than 0,05 ng/kg
1,2,3,6,7,8-HxCDF	less than 0,05 ng/kg
2,3,4,6,7,8-HxCDF	less than 0,05 ng/kg
1,2,3,7,8,9-HxCDF	less than 0,05 ng/kg
1,2,3,4,6,7,8-HpCDF	less than 0,05 ng/kg
1,2,3,4,7,8,9-HpCDF	less than 0,05 ng/kg
OCDF	less than 0,2 ng/kg
TEQ (WHO 2005) PCDD/F excl. LOQ	0,000 ng/kg
TEQ (WHO 2005) PCDD/F incl. LOQ	0,158 ng/kg
WHO (2005)-PCDD/F + PCB TEQ incl. LOQ (food)	0,272 ng/kg
Moisture percentage used for calculation to 12% moisture	0,30 %
TEQ (WHO 2005) PCDD/F excl. LOQ (feed) 12% moisture	0,000 ng/kg
TEQ (WHO 2005) PCDD/F incl. LOQ (feed) 12% moisture	0,139 ng/kg
WHO (2005)-PCDD/F + PCB TEQ incl. feed 12% moisture	0,240 ng/kg
Results of analysis performed in fat, expressed as ng/kg fat.	.

Approved by: FH

Dioxin-like PCBs (GC-HR/MS, in-house method NL/22a/b, NEN-EN 16215 (feed), Regulation EU2017/771 (feed) & EU 2017/664 (food))

PCB 77	2,1 ng/kg
PCB 81	less than 2 ng/kg
PCB 126	less than 0,5 ng/kg
PCB 169	less than 2 ng/kg
PCB 105	less than 10 ng/kg
PCB 114	less than 10 ng/kg
PCB 118	20,7 ng/kg
PCB 123	less than 10 ng/kg
PCB 156	less than 10 ng/kg
PCB 157	less than 10 ng/kg
PCB 167	less than 10 ng/kg
PCB 189	less than 10 ng/kg
PCB -TEQ (WHO 2005) excl. LOQ (food)	0,001 ng/kg
PCB -TEQ (WHO 2005) incl. LOQ (food)	0,114 ng/kg

: accredited method (accreditation number L440)

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Certificate No. 201808571
Date : 06-03-2018

Approved by: FH

Dioxin-like PCBs (GC-HR/MS, in-house method NL/22a/b, NEN-EN 16215 (feed), Regulation EU2017/771 (feed) & EU 2017/664 (food))

Moisture percentage used for calculation to 12% moisture	0,3 %
PCB-TEQ (WHO 2005) excl. LOQ (feed) 12% moisture	0,001 ng/kg
PCB-TEQ (WHO 2005) incl. LOQ (feed) 12% moisture	0,101 ng/kg

Polychlorinated Biphenyls

Approved by: FH

Non-dioxin-like PCBs (GC-HR/MS, in-house method NL/22a/b, NEN-EN 16215 (feed), Regulation EU2017/771 (feed) & EU 2017/664 (food))

PCB 28	0,1 µg/kg
PCB 52	less than 0,1 µg/kg
PCB 101	less than 0,1 µg/kg
PCB 138	less than 0,1 µg/kg
PCB 153	less than 0,1 µg/kg
PCB 180	less than 0,1 µg/kg
PCB SUM (PCB 28, 52, 101, 138, 153, 180)	less than 0,6 µg/kg
SUM : (PCB 28,52,101,138,153,180) (feed) 12% moisture	less than 0.5 µg/kg

Solvents

Approved by: JM

Solvents (GC-MS)

1,1 Dichloroethylene	less than 1 mg/kg
1,2 Dichloroethane	less than 1 mg/kg
1,1,1 Trichloroethane 71-55-6	less than 1 mg/kg
2,3 Dimethylpentane	less than 1 mg/kg
Acetone 67-64-1	less than 1 mg/kg
Benzene 71-43-2	less than 1 mg/kg
Bis Phenol A 80-05-7	less than 1 mg/kg
Butylacrylate 58152-79-7	less than 1 mg/kg
Butylbenzene	less than 1 mg/kg
Chloroform 67-66-3	less than 1 mg/kg
Carbontetrachloride 56-23-5	less than 1 mg/kg
Cyclohexane	less than 1 mg/kg
Decane 124-71-7	less than 1 mg/kg
Dichloromethane	less than 1 mg/kg
Ethanol 64-17-5	less than 1 mg/kg
Ethylacrylate 140-88-5	less than 1 mg/kg
Ethylacetate 140-88-5	less than 1 mg/kg

: accredited method (accreditation number L440)

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Date : 06-03-2018

Approved by: JM

Solvents (GC-MS)	
Hexane, incl. isomers	less than 1 mg/kg
Ethylbenzene 100-41-4	less than 1 mg/kg
Heptanal 111-71-7	less than 1 mg/kg
Hexanal 66-25-1	less than 1 mg/kg
Heptane 142-82-5	less than 1 mg/kg
m+p-Xylene	less than 1 mg/kg
Iso-propanol 67-63-0	less than 1 mg/kg
iso-hexane 92112-69-1	less than 1 mg/kg
Methylcyclopentane 96-37-7	less than 1 mg/kg
Methylacrylate 96-33-3	less than 1 mg/kg
Methanol 67-56-1	less than 1 mg/kg
Methylcyclohexane 108-87-2	less than 1 mg/kg
Methylethylketone 78-93-3	less than 1 mg/kg
Octane 111-65-9	less than 1 mg/kg
o-Xylene 95-47-6	less than 1 mg/kg
Pentanal 110-62-3	less than 1 mg/kg
Pentane 109-66-0	less than 1 mg/kg
Styrene 100-42-5	less than 1 mg/kg
Tetrachloroethene	less than 1 mg/kg
Toluene 108-88-3	less than 1 mg/kg
Trichloroethene	less than 1 mg/kg
General	

Approved by: FH

Moisture for Dioxin recalculation	
Moisture	0,30 %

Approved by: JM

Erucic acid C 22:1 (In accordance with ISO 12966-2 / ISO 12966-4), NL/16	
Erucic acid (In accordance with ISO 12966-2 / ISO 12966-4), NL/16	0,0 %

Approved by: JM

3-MCPD (ISO/CD 18363.2 AOCS Official Method Cd 29c-13)	
3-MCPD	0,0337 mg/kg
Other analysis	

Approved by: JM

Glycidyl-Ester (ISO/CD 18363.2)	
Glycidyl-Ester (ISO/CD 18363.2)	less than 0,01 mg/kg

; accredited method (accreditation number L440)

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Sub1, sub2, sub3 etc.: This version of the report is a subversion.

NofaLab
laboratories

Certificate No. **201808571**
Date : 06-03-2018

Nofalab B.V.
M. Bruggeman
Director

; accredited method (accreditation number L440)
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NofaLab is a member of NofaGroup

NOFALAB
Laboratories

SternChemie GmbH & Co KG
An der Alster 81

20099 Hamburg
Germany

Certificate of Analysis

No. 2019043829

Date: 27-8-2019

Instruction received on	21-8-2019
Sample received	21-8-2019
Product	Sunflower lecithin
Packing	1 Plastic bottle
Sample quantity	1 l
Sample temperature	Ambient
Sample sealed	No
Markings	
Sample description	LeciStar S 100, PSC021669, Tank 16

Test Results:

2019043829.00

Package

3-MCPD	0,089 mg/kg

Glycidyl ester

Glycidyl ester	Less than 0,05 mg/kg
Sum 3-MCPD and Glycidyl ester	95 ppb

Package

Dioxins

WHO PCDD/F-TEQ excl. LOQ 2005	0,000 pg/g fat
WHO PCDD/F-TEQ incl. LOQ 2005	0,158 pg/g fat
WHO PCDD/F + DL-PCBs TEQ excl. LOQ 2005	0,002 pg/g fat
WHO PCDD/F + DL-PCBs TEQ incl. LOQ 2005	0,273 pg/g fat
Polychlorinated dibenzodioxins	
2,3,7,8-TCDD (1746-01-6)	Less than 0,050 pg/g fat
1,2,3,7,8-PeCDD (40321-76-4)	Less than 0,050 pg/g fat
1,2,3,4,7,8-HxCDD (39227-28-6)	Less than 0,050 pg/g fat

: accredited method (accreditation number L440)

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CERTIFICATE OF ANALYSIS

1,2,3,6,7,8-HxCDD (57653-85-7)	Less than 0,050 pg/g fat
1,2,3,7,8,9-HxCDD (19408-74-3)	Less than 0,050 pg/g fat
1,2,3,4,6,7,8-HpCDD (35822-46-9)	Less than 0,050 pg/g fat
OCDD (3268-87-9)	Less than 0,200 pg/g fat
Polychlorinated dibenzofurans	
2,3,7,8-TCDF (51207-31-9)	Less than 0,050 pg/g fat
1,2,3,7,8-PeCDF (57117-41-6)	Less than 0,050 pg/g fat
2,3,4,7,8-PeCDF (57117-31-4)	Less than 0,050 pg/g fat
1,2,3,4,7,8-HxCDF (70648-26-9)	Less than 0,050 pg/g fat
1,2,3,6,7,8-HxCDF (57117-44-9)	Less than 0,050 pg/g fat
2,3,4,6,7,8-HxCDF (60851-34-5)	Less than 0,050 pg/g fat
1,2,3,7,8,9-HxCDF (72918-21-9)	Less than 0,050 pg/g fat
1,2,3,4,6,7,8-HpCDF (67562-39-4)	Less than 0,050 pg/g fat
1,2,3,4,7,8,9-HpCDF (55673-89-7)	Less than 0,050 pg/g fat
OCDF (39001-02-0)	Less than 0,200 pg/g fat

Dioxin like PCB's

PCB 77 (80333-65-9)	Less than 2,000 pg/g fat
PCB 81 (70362-50-4)	Less than 2,000 pg/g fat
PCB 126 (57465-28-8)	Less than 0,500 pg/g fat
PCB 169 (56-25-7)	Less than 2,000 pg/g fat
PCB 105 (35899-54-8)	21,410 pg/g fat
PCB 114 (74472-37-0)	Less than 10,000 pg/g fat
PCB 118 (31508-00-6)	51,640 pg/g fat
PCB 123 (65510-44-3)	Less than 10,000 pg/g fat
PCB 156 (38380-08-4)	Less than 10,000 pg/g fat
PCB 157 (69782-90-7)	Less than 10,000 pg/g fat
PCB 167 (52663-72-6)	Less than 10,000 pg/g fat
PCB 189 (39635-31-9)	Less than 10,000 pg/g fat
WHO-PCB-TEQ (WHO 2005) excl. LOQ	0,002 pg/g fat
WHO-PCB-TEQ (WHO 2005) incl. LOQ	0,115 pg/g fat

Non dioxine like PCB's

PCB 28 (7012-37-5)	Less than 0,100 ng/g fat
PCB 52 (35693-99-3)	Less than 0,100 ng/g fat
PCB 101 (37680-73-2)	Less than 0,100 ng/g fat
PCB 138 (35065-28-2)	Less than 0,100 ng/g fat
PCB 153 (8020-83-5)	Less than 0,100 ng/g fat
PCB 180 (35065-29-3)	Less than 0,100 ng/g fat
PCB SUM (PCB 28, 52, 101, 138, 153, 180) incl.LOQ	Less than 0,600 ng/g fat

Metals

Arsenic (As) (7440-38-2)	0,02 mg/kg

: accredited method (accreditation number L440)

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Cadmium (Cd) (7440-43-9)	Less than 0,01 mg/kg
Heavy metals expressed as lead (Pb)	
Heavy metals expressed as lead	Less than 10 mg/kg
Lead (Pb) (7439-92-1)	Less than 0,01 mg/kg
Mercury (Hg) (7439-97-6)	0,02 mg/kg

Mycotoxin

Aflatoxin Total	
Aflatoxin B1 (1162-65-8)	Less than 0,5 µg/kg
Aflatoxin Total B1, B2, G1 and G2	Less than 2 µg/kg
Ochratoxin A (303-47-9)	Less than 0,5 µg/kg

Pesticides

Pesticide Package 1: Pesticides Flexible scope Organic analyses (multiresidue methode GC-MS/MS, LC-MS/MS positive mode) NL/10a/b/c (in accordance with EN 15662). Acc. to the Nofalab pesticides list version: 01-01-2019	Not detected
Pesticides (Components analysed and reported upon customer request, out of package 06), (Ionic Pesticides analyses individual parameters) NL/10d in accordance with QUPPE SRM method. Acc. to the Nofalab pesticides list version: 01-01-2019	
Glycine derivative	
Glyphosate (1071-83-6)	0,052 mg/kg
Pesticides (Components analysed and reported upon customer request, out of package 07), (Ionic Pesticides analyses individual parameters) NL/10d in accordance with QUPPE SRM method. Acc. to the Nofalab pesticides list version: 01-01-2019	
Bipyridylium	
Diquat (2764-72-9)	Less than 0,01 mg/kg
Paraquat (4685-14-7)	Less than 0,02 mg/kg

Polycyclic Aromatic Hydrocarbons

PAH's, (Polycyclic Aromatic Hydrocarbons)	
Benzo(a)anthracene (56-55-3)	1,3 µg/kg
Chrysene (218-01-9)	2,0 µg/kg
Benzo(b)fluoranthene (205-99-2)	2,4 µg/kg
Benzo(a)pyrene (50-32-8)	2,0 µg/kg
Sum of PAH-4	7,6 µg/kg
Notification;	Analysis performed on fat content

: accredited method (accreditation number L440)

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