NOFALAB Laboratories

Certificate No. **2019043829**
Date: 27-8-2019

Solvents

VOC (Volatile organic compounds)

1,1,1-Trichloroethane (71-55-6)	Less than 1 mg/kg
1,1-Dichloroethylene (75-35-4)	Less than 1 mg/kg
1,2-Dichloroethane (156-59-2)	Less than 1 mg/kg
2,3-Dimethylpentane	Less than 1 mg/kg
2-Methylpentane (107-83-5)	Less than 1 mg/kg
2-Propanol (67-63-0)	Less than 1 mg/kg
3-Methylpentane (96-14-0)	Less than 1 mg/kg
Acetone (67-64-1)	Less than 1 mg/kg
Benzene (71-43-2)	Less than 1 mg/kg
Butanol (sum) (71-55-6)	Less than 1 mg/kg
Butyl acrylate (58152-79-7)	Less than 1 mg/kg
Butylbenzene (104-51-8)	Less than 1 mg/kg
Carbontetrachloride (56-23-5)	Less than 1 mg/kg
Chloroform (67-66-3)	Less than 1 mg/kg
Cyclohexane (110-82-7)	Less than 1 mg/kg
Dichloromethane (75-09-2)	Less than 1 mg/kg
Ethanol (64-17-5)	Less than 1 mg/kg
Ethyl acetate (140-88-5)	Less than 1 mg/kg
Ethyl acrylate (140-88-5)	Less than 1 mg/kg
Ethylbenzene (100-41-4)	Less than 1 mg/kg
Ethylene	Less than 1 mg/kg
Heptanal (111-71-7)	Less than 1 mg/kg
Hexanal (66-25-1)	Less than 1 mg/kg
Isomers of Hexane, excl. n-hexane	Less than 1 mg/kg
Methanol (67-56-1)	Less than 1 mg/kg
Methyl acrylate (96-33-3)	Less than 1 mg/kg
Methylcyclohexane (108-87-2)	Less than 1 mg/kg
Methylcyclopentane (96-37-7)	Less than 1 mg/kg
Methyle chloride	Less than 1 mg/kg
Methylethylketone (78-93-3)	Less than 1 mg/kg
Naphtalene	Less than 1 mg/kg
n-Decane (124-71-7)	Less than 1 mg/kg
n-Heptane (142-82-5)	Less than 1 mg/kg
n-Hexane	Less than 1 mg/kg
n-Hexane, incl. isomers	Less than 1 mg/kg
n-Octane (111-65-9)	Less than 1 mg/kg
n-Pentane (109-66-0)	Less than 1 mg/kg
o-Xylene (95-47-6)	Less than 1 mg/kg
Pentanal (110-62-3)	Less than 1 mg/kg

: accredited method (accreditation number L440)

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NOFALAB Laboratories

Certificate No. **2019043829**
Date: 27-8-2019

	Styrene (100-42-5)	Less than 1 mg/kg
	Tetrachloroethene	Less than 1 mg/kg
	Tetrachloroethylene (79-01-6)	Less than 1 mg/kg
	Toluene (108-88-3)	Less than 1 mg/kg
	Trichlormethane	Less than 1 mg/kg
	Trichloroethene	Less than 1 mg/kg
	Trichloroethylene (127-18-4)	Less than 1 mg/kg
	Xylene	Less than 1 mg/kg
	Sum of chlorated solvents	Less than 2 mg/kg
	Sum of m-Xylene and p-Xylene (m;108-38-3 p;106-42-3)	Less than 1 mg/kg
	Methyl Acetate	Less than 1 mg/kg
	Total VOC (Volatile Organic Compounds)	Less than 1 mg/kg

: accredited method (accreditation number L440)

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Certificate No. **2019043829**
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 volatile organic compounds**
Analysis	VOC (Volatile organic compounds)
Norm	Equivalent to ISO 15303
WI	NL/15
Device	HS GC-MS
Method	**Determination of volatile organic compounds**
Analysis	VOC (Volatile organic compounds)
Norm	Equivalent to ISO 15303
WI	NL/15
Device	HS GC-MS
Method	**Determination of metals**
Analysis	Arsenic (As),Heavy metals expressed as lead (Pb),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	**Determination of the content of mycotoxins**
Analysis	Aflatoxin Total (B1 & Total Reportable),Ochratoxin A
Norm	In-house method
WI	NL/13
Device	LC-MS/MS

Sample preparation

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

: accredited method (accreditation number L440)

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Certificate No. **2019043829**
Date: 27-8-2019

ANNEX

Sample Determination

Method	**QuPPe and QuPPe- AO**
Analysis	Pesticides Package 06 (Components requested),Pesticides Package 07 (Components requested)
Norm	In accordance with QuPPe and QuPPe-AO
WI	NL/10d
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
Method	**Determination of fatty-acid-bound 3-chloropropane-1,2-diol (3-MCPD), glycidol- and glycidyl-esters**
Analysis	3-MCPD,Glycidyl ester
Norm	In-house method
WI	NL/44a
Device	PAL/GC-MS
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

Method	**Dioxins sample preparation (Food)**
Norm	In-house method
WI	NL/22a
Method	**Extraction of 3-MCPD & Glycidyl Ester**
Norm	Equivalent to ISO 18363-1 and AOCS Cd 29c-13
WI	NL/44a

Nofalab
M. Bruggeman
Director

: accredited method (accreditation number L440)

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Laboratories

SternChemie GmbH & Co KG
An der Alster 81

20099 Hamburg
Germany

Certificate of Analysis

No. 2019046727

Date: 6-9-2019

Instruction received on	3-9-2019
Sample received	3-9-2019
Product	De-oiled lecithin
Packing	16 Plastic bottle
Sample quantity	16 Pieces
Sample temperature	Ambient
Sample sealed	No

Markings

Sample description	SternPur S P
Batch number	PSC021836
Sample	De-Oiled Sunflower Lecithin Powder

Test Results:

2019046727.00

Package

3-MCPD	Less than 0,05 mg/kg
Glycidyl ester	
Glycidyl ester	Less than 0,05 mg/kg
Sum 3-MCPD and Glycidyl ester	Less than 50 ppb

Package

Dioxins	
WHO PCDD/F-TEQ excl. LOQ 2005	0,004 pg/g fat
WHO PCDD/F-TEQ incl. LOQ 2005	0,161 pg/g fat
WHO PCDD/F + DL-PCBs TEQ excl. LOQ 2005	0,004 pg/g fat
WHO PCDD/F + DL-PCBs TEQ incl. LOQ 2005	0,275 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

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CERTIFICATE OF ANALYSIS

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)	0,330 pg/g fat
OCDD (3268-87-9)	1,190 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)	0,060 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)	Less than 10,000 pg/g fat
PCB 114 (74472-37-0)	Less than 10,000 pg/g fat
PCB 118 (31508-00-6)	Less than 10,000 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	0,000 pg/g fat
WHO-PCB-TEQ (WHO 2005) incl. LOQ	0,113 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)	Less than 0,01 mg/kg

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

Pesticides

Pesticide Package 6: Ionic Pesticides analyses individual parameters NL/10d (in accordance with QUPPE SRM method). Acc. to the Nofalab pesticides list version: 01-01-2019	Not detected
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

Benzo(a)pyrene	
Benzo(a)pyrene (50-32-8)	Less than 0,1 µg/kg
Notification;	Analysis performed on fat content
PAH's, (Polycyclic Aromatic Hydrocarbons)	
Benzo(a)anthracene (56-55-3)	Less than 0,1 µg/kg
Chrysene (218-01-9)	Less than 0,1 µg/kg
Benzo(b)fluoranthene (205-99-2)	Less than 0,1 µg/kg
Benzo(a)pyrene (50-32-8)	Less than 0,1 µg/kg
Sum of PAH-4	Not detected µg/kg
Notification;	Analysis performed on fat content

Solvents

VOC (Volatile organic compounds)	
1,1,1-Trichloroethane (71-55-6)	Less than 1 mg/kg
1,1-Dichloroethylene (75-35-4)	Less than 1 mg/kg
1,2-Dichloroethane (156-59-2)	Less than 1 mg/kg

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2,3-Dimethylpentane	Less than 1 mg/kg
2-Methylpentane (107-83-5)	Less than 1 mg/kg
2-Propanol (67-63-0)	Less than 1 mg/kg
3-Methylpentane (96-14-0)	Less than 1 mg/kg
Acetone (67-64-1)	9,2 mg/kg
Benzene (71-43-2)	Less than 1 mg/kg
Butanol (sum) (71-55-6)	Less than 1 mg/kg
Butyl acrylate (58152-79-7)	Less than 1 mg/kg
Butylbenzene (104-51-8)	Less than 1 mg/kg
Carbontetrachloride (56-23-5)	Less than 1 mg/kg
Chloroform (67-66-3)	Less than 1 mg/kg
Cyclohexane (110-82-7)	Less than 1 mg/kg
Dichloromethane (75-09-2)	Less than 1 mg/kg
Ethanol (64-17-5)	Less than 1 mg/kg
Ethyl acetate (140-88-5)	Less than 1 mg/kg
Ethyl acrylate (140-88-5)	Less than 1 mg/kg
Ethylbenzene (100-41-4)	Less than 1 mg/kg
Ethylene	Less than 1 mg/kg
Heptanal (111-71-7)	Less than 1 mg/kg
Hexanal (66-25-1)	Less than 1 mg/kg
Isomers of Hexane, excl. n-hexane	Less than 1 mg/kg
Methanol (67-56-1)	Less than 1 mg/kg
Methyl acrylate (96-33-3)	Less than 1 mg/kg
Methylcyclohexane (108-87-2)	Less than 1 mg/kg
Methylcyclopentane (96-37-7)	Less than 1 mg/kg
Methyle chloride	Less than 1 mg/kg
Methylethylketone (78-93-3)	Less than 1 mg/kg
Naphtalene	Less than 1 mg/kg
n-Decane (124-71-7)	Less than 1 mg/kg
n-Heptane (142-82-5)	Less than 1 mg/kg
n-Hexane	Less than 1 mg/kg
n-Hexane, incl. isomers	Less than 1 mg/kg
n-Octane (111-65-9)	Less than 1 mg/kg
n-Pentane (109-66-0)	Less than 1 mg/kg
o-Xylene (95-47-6)	Less than 1 mg/kg
Pentanal (110-62-3)	Less than 1 mg/kg
Styrene (100-42-5)	Less than 1 mg/kg
Tetrachloroethene	Less than 1 mg/kg
Tetrachloroethylene (79-01-6)	Less than 1 mg/kg
Toluene (108-88-3)	Less than 1 mg/kg
Trichlormethane	Less than 1 mg/kg
Trichloroethene	Less than 1 mg/kg
Trichloroethylene (127-18-4)	Less than 1 mg/kg

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	Xylene	Less than 1 mg/kg
	Sum of chlorated solvents	Less than 2 mg/kg
	Sum of m-Xylene and p-Xylene (m;108-38-3 p;106-42-3)	Less than 1 mg/kg
	Methyl Acetate	Less than 1 mg/kg
	Total VOC (Volatile Organic Compounds)	9,2 mg/kg

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Certificate No. **2019046727**
Date: 6-9-2019

ANNEX

Sample Determination

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 volatile organic compounds**
Analysis	VOC (Volatile organic compounds)
Norm	Equivalent to ISO 15303
WI	NL/15
Device	HS GC-MS
Method	**QuPPe and QuPPe- AO**
Analysis	Pesticides Package 06,Pesticides Package 07 (Components requested)
Norm	In accordance with QuPPe and QuPPe-AO
WI	NL/10d
Device	LC-MS/MS
Method	**Determination of metals**
Analysis	Cadmium (Cd),Lead (Pb),Arsenic (As),Mercury (Hg)
Norm	In-house method
WI	NL/26
Device	ICP-MS
Method	**Determination of volatile organic compounds**
Analysis	VOC (Volatile organic compounds)
Norm	Equivalent to ISO 15303
WI	NL/15
Device	HS GC-MS
Method	**Determination of the content of PolycyclicAromaticHydrocarbons (PAH's)**
Analysis	PAH's, (Polycyclic Aromatic Hydrocarbons),Benzo(a)pyrene
Norm	In accordance with ISO 22959
WI	NL/03
Device	DACC-HPLC Fluorescence
Method	**Determination of the content of mycotoxins**
Analysis	Aflatoxin Total (B1 & Total Reportable),Ochratoxin A
Norm	In-house method
WI	NL/13
Device	LC-MS/MS

Sample preparation

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

: accredited method (accreditation number L440)

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Certificate No. **2019046727**
Date: 6-9-2019

ANNEX

Sample Determination

Method	**Non dioxin-like PCB's**
Analysis	Non dioxine like PCB's
Norm	In-house method
WI	NL/22b
Device	GC-HR/MS
Method	**Determination of fatty-acid-bound 3-chloropropane-1,2-diol (3-MCPD), glycidol- and glycidyl-esters**
Analysis	3-MCPD,Glycidyl ester
Norm	In-house method
WI	NL/44a
Device	PAL/GC-MS
Method	**Determination of the content of PolycyclicAromaticHydrocarbons (PAH's) in extracted fat**
Analysis	Benzo(a)pyrene,PAH's, (Polycyclic Aromatic Hydrocarbons)
Norm	In accordance with ISO 22959
WI	NL/03

Sample preparation

Method	**Dioxins sample preparation (Food)**
Norm	In-house method
WI	NL/22a
Method	**Extraction of 3-MCPD & Glycidyl Ester**
Norm	Equivalent to ISO 18363-1 and AOCS Cd 29c-13
WI	NL/44a

Nofalab
M. Bruggeman
Director

: accredited method (accreditation number L440)

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Results reported are expressed in product unless clearly stated otherwise.

NofaLab
laboratories

SternChemie GmbH & Co KG
An der Alster 81

20099 Hamburg
Germany

Certificate of Analysis

No. 2018024538

Date: 25-10-2018

Instruction received on	19-10-2018
Sample received	22-10-2018
Product	Sunflower lecithin powder
Packing	1 Plastic bag
Sample quantity	501 g
Sample temperature	Ambient
Sample sealed	No
Markings	
Sample description	SternPur S P 200 PSC019616

Test Results:

2018024538.00

Package	
2-MCPD	Less than 0,01 mg/kg
3-MCPD	Less than 0,01 mg/kg
Glycidyl ester	Less than 0,01 mg/kg
Chromatography	
Bisphenol A	
Bisphenol A (BPA) (80-05-7)	Less than 0,01 mg/kg
Ethyl acrylate (140-88-5)	Less than 1 mg/kg
Dioxins	
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

: accredited method (accreditation number L440)

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PCB 169 (56-25-7)	Less than 2,000 pg/g fat
PCB 105 (35899-54-8)	Less than 10,000 pg/g fat
PCB 114 (74472-37-0)	Less than 10,000 pg/g fat
PCB 118 (31508-00-6)	Less than 10,000 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	0,000 pg/g fat
WHO-PCB-TEQ (WHO 2005) incl. LOQ	0,113 pg/g fat

Dioxins

WHO PCDD/F-TEQ excl. LOQ 2005	0,007 pg/g fat
WHO PCDD/F-TEQ incl. LOQ 2005	0,164 pg/g fat
WHO PCDD/F + DL-PCBs TEQ excl. LOQ 2005	0,007 pg/g fat
WHO PCDD/F + DL-PCBs TEQ incl. LOQ 2005	0,278 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)	0,62 pg/g fat
OCDD (3268-87-9)	2,05 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

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

: accredited method (accreditation number L440)

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PCB SUM (PCB 28, 52, 101, 138, 153, 180)	Less than 0,600 ng/g fat
Fatty acid composition	
C22:1 Erucic acid (112-86-7)	0,1 %
Metals	
Arsenic (As) (7440-38-2)	0,01 mg/kg
Cadmium (Cd) (7440-43-9)	0,03 mg/kg
Heavy metals expressed as lead (Pb)	
Heavy metals expressed as lead	Less than 10 mg/kg
Lead (Pb) (7439-92-1)	0,02 mg/kg
Mercury (Hg) (7439-97-6)	Less than 0,01 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: 01-01-2018	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.	
Glycine derivative	
Glyphosate (1071-83-6)	Less than 0,015 mg/kg
Polycyclic Aromatic Hydrocarbons	
Benzo(a)pyrene	
Benzo(a)pyrene (50-32-8)	Less than 0,1 µg/kg
Notification;	Analysis performed on fat content
PAH's, (Polycyclic Aromatic Hydrocarbons)	
Benzo(a)anthracene (56-55-3)	Less than 0,1 µg/kg
Chrysene (218-01-9)	Less than 0,1 µg/kg
Benzo(b)fluoranthene (205-99-2)	Less than 0,1 µg/kg
Benzo(a)pyrene (50-32-8)	Less than 0,1 µg/kg

: accredited method (accreditation number L440)

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NofaLab laboratories

Certificate No. **2018024538**
Date: 25-10-2018

Sum of PAH-4	Not detected µg/kg
Notification;	Analysis performed on fat content

Solvents

Q	**1,1,1-Trichloroethane (71-55-6)**	Less than 1 mg/kg
	1,1-Dichloroethylene (75-35-4)	Less than 1 mg/kg
	1,2-Dichloroethane (156-59-2)	Less than 1 mg/kg
	2-Propanol (67-63-0)	Less than 1 mg/kg
	Acetone (67-64-1)	14,6 mg/kg
Q	**Benzene (71-43-2)**	Less than 1 mg/kg
	Butyl acrylate (58152-79-7)	Less than 1 mg/kg
	Butylbenzene (104-51-8)	Less than 1 mg/kg
Q	**Carbontetrachloride (56-23-5)**	Less than 1 mg/kg
Q	**Chloroform (67-66-3)**	Less than 1 mg/kg
	Cyclohexane (110-82-7)	Less than 1 mg/kg
	Dichloromethane (75-09-2)	Less than 1 mg/kg
	Ethanol (64-17-5)	12,1 mg/kg
	Ethylacetate	
	Ethyl acetate (140-88-5)	Less than 1 mg/kg
Q	**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
Q	**Isomers of Hexane, excl. n-hexane**	Less than 1 mg/kg
	Methanol (67-56-1)	Less than 1 mg/kg
	Methyl acrylate (96-33-3)	Less than 1 mg/kg
	Methylcyclohexane (108-87-2)	Less than 1 mg/kg
Q	**Methylcyclopentane (96-37-7)**	Less than 1 mg/kg
	Methylethylketone (78-93-3)	Less than 1 mg/kg
	n-Decane (124-71-7)	Less than 1 mg/kg

Q : accredited method (accreditation number L440)

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Certificate No. **2018024538**
Date: 25-10-2018

n-Heptane (142-82-5)	Less than 1 mg/kg
n-Hexane, incl. isomers	Less than 1 mg/kg
n-Octane (111-65-9)	Less than 1 mg/kg
n-Pentane (109-66-0)	Less than 1 mg/kg
o-Xylene (95-47-6)	Less than 1 mg/kg
Pentanal (110-62-3)	Less than 1 mg/kg
Styrene (100-42-5)	Less than 1 mg/kg
Sum of m-Xylene and p-Xylene (m;108-38-3 p;106-42-3)	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

: accredited method (accreditation number L440)

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Certificate No. **2018024538**
Date: 25-10-2018

ANNEX

Sample Determination | **Sample preparation**

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 volatile organic compounds**
Analysis	Sum of m-Xylene and p-Xylene,n-Hexane, incl. isomers,1,2-Dichloroethane,Methyl acrylate,Toluene,Hexanal,Methylethylketone,2-Propanol,Isomers of Hexane, excl. n-hexane,Styrene,Acetone,Ethylacetate,Tetrachloroethene,o-Xylene,Heptanal,Ethyl acrylate,Cyclohexane,Butyl acrylate,Benzene,Chloroform,n-Octane,Carbontetrachloride,n-Pentane,n-Decane,n-Heptane,Methylcyclohexane,1,1,1-Trichloroethane,Pentanal,1,1-Dichloroethylene,Ethylbenzene,Dichloromethane,Ethanol,Trichloroethene,Methylcyclopentane,Butylbenzene
Norm	Equivalent to ISO 15303
WI	NL/15
Device	HS GC-MS
Method	**Determination of volatile organic compounds**
Analysis	Methanol
Norm	Equivalent to ISO 15303
WI	NL/15
Device	HS GC-MS
Method	**Determination of metals**
Analysis	Arsenic (As),Heavy metals expressed as lead (Pb),Cadmium (Cd),Mercury (Hg),Lead (Pb)
Norm	In-house method
WI	NL/27
Device	ICP-MS

: accredited method (accreditation number L440)

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NofaLab laboratories

Certificate No. 2018024538
Date: 25-10-2018

ANNEX

Sample Determination | **Sample preparation**

Method	**Determination of fatty-acid composition**
Analysis	C22:1 Erucic acid
Norm	In accordance with ISO 12966-2;ISO 12966-4
WI	NL/16
Device	GC-FID
Method	**Determination of the content of PolycyclicAromaticHydrocarbons (PAH's)**
Analysis	PAH's, (Polycyclic Aromatic Hydrocarbons),Benzo(a)pyrene
Norm	In accordance with ISO 22959
WI	NL/03
Device	DACC-HPLC Fluorescence
Method	**Determination of the content of mycotoxins**
Analysis	Aflatoxin Total (B1 & Total Reportable),Ochratoxin A
Norm	In-house method
WI	NL/13
Device	LC-MS/MS
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 fatty-acid-bound chloroproanediols (MCPD's), glycidol- and glycidyl-esters**
Analysis	2-MCPD,3-MCPD,Glycidyl ester
Norm	Equivalent to ISO 18363-1 and AOCS Cd 29c-13
WI	NL/44A
Device	GC-MS
Method	**Non dioxin-like PCB's**
Analysis	Non dioxine like PCB's
Norm	In-house method
WI	NL/22b
Device	GC-HR/MS

: accredited method (accreditation number L440)

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NofaLab
laboratories

Certificate No. **2018024538**
Date: 25-10-2018

ANNEX

Sample Determination

Method	**Determination of the content of PolycyclicAromaticHydrocarbons (PAH's) in extracted fat**
Analysis	PAH's, (Polycyclic Aromatic Hydrocarbons),Benzo(a)pyrene
Norm	In accordance with ISO 22959
WI	NL/03
Method	**Detetermination of phthalates and phenols**
Analysis	Bisphenol A
Norm	In-house method
WI	NL/48
Device	LC-MS/MS

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. 201737454

Date : 24-10-2017

Instruction received on	:	19-10-2017
Sample received	:	19-10-2017
Sample said to be	:	Sunflower lecithine
Packing	:	Plastic Bag
Sample quantity	:	520,00 gr
Sample temperature	:	Ambient
Sample sealed	:	No
Marked	:	SternPur S P PSC 017108

Test Results:

Approved by: JM

Polycyclic Aromatic Hydrocarbons: DACC-HPLC fluorescence, in accordance with CEN/TS 16621; ISO 22959, NL/03

Benzo(a)pyrene	less than 0,1 µg/kg
Benzo(a)anthracene	less than 0,1 µg/kg
Benzo(b)fluoranthene	less than 0,1 µg/kg
Chrysene	less than 0,1 µg/kg
Sum of PAH-4	not detected µg/kg

Mycotoxins

Approved by: ER

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: ER

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

Ochratoxin A	9,8 µg/kg

Metal and Element analysis

Approved by: ER

: accredited method (accreditation number L440)

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

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laboratories

Certificate No. 201737454
Date : 24-10-2017

	Approved by: ER
Arsenic	
Arsenic (As) (ICP-MS, NEN-EN 13805, in-house method NL/26)	0,02 mg/kg
	Approved by: ER
Cadmium	
Cadmium (Cd) (ICP-MS, NEN-EN 13805, in-house method NL/26)	0,03 mg/kg
	Approved by: ER
Mercury	
Mercury (Hg) (ICP-MS, NEN-EN 13805; in-house method NL/26)	less than 0,01 mg/kg
	Approved by: ER
Lead	
Lead (Pb) (ICP-MS, NEN-EN 13805, in-house method NL/26)	0,01 mg/kg
	Approved by: ER
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 4.1 d 04-07-2017)	
Pesticides (Multi Method, P1)	Not Detected
	Approved by: ER
Ionic Pesticides analyses individual parameters NL/10d (in accordance with QUPPE SRM method).	
Pesticides (Single Residue Method, Ion, P6)	Not Detected
Glyphosate 1071-83-6	less than 0,03 mg/kg
	Approved by: JM
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	0,06 ng/kg
OCDD	less than 0,2 ng/kg
Polychlorinated dibenzofurans	.
2,3,7,8-TCDF	less than 0,05 ng/kg

: accredited method (accreditation number L440)

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

1,2,3,7,8-PeCDF	less than 0,05	ng/kg
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	0,001	ng/kg
TEQ (WHO 2005) PCDD/F incl. LOQ	0,158	ng/kg
WHO (2005)-PCDD/F + PCB TEQ incl. LOQ (food)	0,271	ng/kg
Moisture percentage used for calculation to 12% moisture	1,51	%
TEQ (WHO 2005) PCDD/F excl. LOQ (feed) 12% moisture	0,001	ng/kg
TEQ (WHO 2005) PCDD/F incl. LOQ (feed) 12% moisture	0,141	ng/kg
WHO (2005)-PCDD/F + PCB TEQ incl. feed 12% moisture	0,242	ng/kg

Approved by: JM

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	less than 2	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	less than 10	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 1)	0,000	ng/kg
PCB -TEQ (WHO 2005) incl. LOQ (food 1)	0,113	ng/kg

: accredited method (accreditation number L440)

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A, B, C etc.: This version of the certificate cancels and replaces all previous versions.
Sub1, sub2, sub3 etc.: This version of the report is a subversion.

NofaLab
laboratories

Certificate No. **201737454**
Date : 24-10-2017

Approved by: JM

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	1,51 %
PCB-TEQ (WHO 2005) excl. LOQ (feed) 12% moisture	0,000 ng/kg
PCB-TEQ (WHO 2005) incl. LOQ (feed) 12% moisture	0,101 ng/kg

Polychlorinated Biphenyls

Approved by: JM

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	less than 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

General

Approved by: JM

Moisture for Dioxin recalculation

Moisture	1,51 %

Approved by: ER

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	0,01 %

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. 2020002642

Date: 21-1-2020

Instruction received on	16-1-2020
Sample received	16-1-2020
Product	Lecithin
Packing	1 Plastic jar
Sample quantity	175 ml
Sample temperature	Ambient
Sample sealed	No
Markings	
Sample description	SternPhil S DH 50 PSC020071

Test Results:

Metals

Arsenic (As) (7440-38-2)	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)	Less than 0,01 mg/kg

: 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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NOFALAB Laboratories

Certificate No. **2020002642**
Date: 21-1-2020

ANNEX

Sample Determination

Method	**Determination of metals**
Analysis	Arsenic (As),Heavy metals expressed as lead (Pb),Mercury (Hg),Lead (Pb)
Norm	In-house method
WI	NL/27
Device	ICP-MS

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. 2020002640

Date: 21-1-2020

Instruction received on	16-1-2020
Sample received	16-1-2020
Product	Lecithin
Packing	1 Plastic jar
Sample quantity	175 ml
Sample temperature	Ambient
Sample sealed	No
Markings	
Sample description	SternPhil S DH 50 PSC019451

Test Results:

Metals

Arsenic (As) (7440-38-2)	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)	Less than 0,01 mg/kg

: accredited method (accreditation number L440)

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NOFALAB Laboratories

Certificate No. **2020002640**
Date: 21-1-2020

ANNEX

Sample Determination

Method	**Determination of metals**
Analysis	Arsenic (As),Heavy metals expressed as lead (Pb),Mercury (Hg),Lead (Pb)
Norm	In-house method
WI	NL/27
Device	ICP-MS

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. 2020002644

Date: 21-1-2020

Instruction received on	16-1-2020
Sample received	16-1-2020
Product	Lecithin
Packing	1 Plastic jar
Sample quantity	175 ml
Sample temperature	Ambient
Sample sealed	No
Markings	
Sample description	SternPhil S DH 50 PSC022227

Test Results:

Metals

Arsenic (As) (7440-38-2)	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)	Less than 0,01 mg/kg

: 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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Certificate No. **2020002644**
Date: 21-1-2020

ANNEX

Sample Determination

Method	**Determination of metals**
Analysis	Arsenic (As),Heavy metals expressed as lead (Pb),Mercury (Hg),Lead (Pb)
Norm	In-house method
WI	NL/27
Device	ICP-MS

Sample preparation

Nofalab B.V.
M. Bruggeman
Director

: accredited method (accreditation number L440)

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APPENDIX B

Stability Testing Data

Parameter	LeciStar		Sternphil		SternPur	
	Lot PSC017883		Lot PSC019244		Lot PSC017917	
Time	**0**	**12 months**	**0**	**12 months**	**0**	**12 months**
Acetone Insolubles (%)	62.2	62.2	56.76	56.6	96.7	96.2
Moisture (%)	0.34	0.47	0.55	0.46	1.16	1.8
Peroxide Value (meq/kg)	0	1	0	0	0	0.2
Acid Value (mg KOH/g)	25.7	25.2	40.62	40.3	29.8	30.4
Color (Gardner 10%)	12	12	12.5	12	NA	NA
Total plate count (cfu/g)	30	<10	<10	<10	170	10
Yeasts (cfu/g)	<10	<10	<10	<10	40	10
Molds (cfu/g)	<10	10	<10	<10	<10	10
Escherichia coli (/g)	Negative	Negative	Negative	Negative	Negative	Negative
Salmonella (/25 g)	Negative	Negative	Negative	Negative	Negative	Negative

NA = not applicable

EXHIBIT 1

Report of the Expert Panel

OPINION OF A GRAS PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF SUNFLOWER LECITHIN FOR USE AS AN INGREDIENT IN HUMAN FOOD

Introduction

An independent panel of experts (GRAS Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by Sternchemie GmbH & Co. KG (Sternchemie) to determine the safety and Generally Recognized as Safe (GRAS) status of the use of sunflower lecithin for use in food for human consumption. Sunflower lecithin is intended for use as an emulsifier, dispersing agent, wetting agent, and as a release agent in foods. The sunflower lecithin ingredient is manufactured in accordance with current Good Manufacturing Practice (cGMP) and meets the proposed specifications.

A detailed review based on the existing scientific literature (through December 2019) on the safety of lecithin and sunflower lecithin was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The GRAS Panel members reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on January 9, 2020 via teleconference. Based on their independent, critical evaluation of all of the available information, the GRAS Panel unanimously concluded that the intended uses and use levels described herein for Sternchemie's sunflower lecithin ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of Sunflower Lecithin for Use in Food**) and manufactured according to cGMP, is safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the GRAS Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

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.

Manufacturing Process

Sunflower seeds are the starting material for Sternchemie's sunflower lecithin. Sternchemie processes crude lecithin to produce standardized, de-oiled (powder), or hydrolyzed sunflower lecithin product forms.

The production of sunflower crude lecithin 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). The solvent is evaporated by use of steam stripping. The solvent-free crude sunflower oil then moves to the next steps including degumming and standardization. It is recommended that the lecithin be standardized in order to produce a consistent composition and functionality. The standardization of sunflower lecithin is usually accomplished by addition of sunflower oil or/and sunflower-based oleic fatty acids.

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" (de-oiled lecithin powder). An acetone-based extraction process is employed and based on the property of polar lipids being almost insoluble in acetone, whereas neutral lipids dissolve easily. Any 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. These products display a significant improvement in emulsifying capacity and in dispersibility in water. A free-flowing agent such as silicon dioxide may be added as necessary.

For certain final applications, the original structure, and consequently the physicochemical and nutritional properties, of phospholipids can be modified by enzymatic hydrolysis (hydrolyzed sunflower lecithin). The enzyme phospholipase A2 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). The production process includes mixing 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.

Analytical (physical, chemical and microbiological) results for the final sunflower lecithin products confirm that the finished products meets the proposed specifications as demonstrated by the consistency of production, the lack of impurities and contaminants (e.g., heavy metals; microbiological contaminants).

The sunflower lecithin products have been tested over a 12-month period and meets the analytical specifications. Sternchemie recommends that the products be stored in a dry place, away from sunlight, at 15- 25°C, in original unopened packaging.

History of Use

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 the 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 (see table below) and 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.

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

Intended Use and Intake Assessment

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.

Safety Data

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, 2006a, and GRN 197; FDA, 2006b), 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.

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, and that no numerical ADI was needed for the general population over 1 year of age (EFSA, 2017).

Due to the extensive safety 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. The safety section of GRN 226 (FDA, 2008) 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.

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.

General Recognition of the Safety of Sunflower Lecithin

The intended use of the sunflower lecithin ingredients has been determined to be safe through scientific procedures as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination, and this determination is based on the following:

- 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.

- The sunflower lecithin products are manufactured from sunflower seeds, 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.

- Specifications for the sunflower lecithin products have been established and minimize the risk of potential contaminants such as heavy metals and microbiological contaminants.

- 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 biological 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, 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.

- 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.

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Sternchemie's sunflower lecithin products as ingredients in food products. We unanimously conclude that the intended use of Sternchemie's sunflower lecithin ingredients, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of Sunflower Lecithin for Use in Food", is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended uses and use levels of the Sternchemie's sunflower lecithin ingredients in foods for human consumption, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in conventional foods specified herein.

It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

_____ _____

Michael Carakostas, DVM, Ph.D. Date
Consultant
MC Scientific Consulting LLC

_____ _____

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

_____ _____

Thomas Vollmuth, Ph.D. Date
Consultant
Vollmuth and Associates, LLC

Conclusions of the GRAS Panel

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It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

[redacted]. January 22, 2020.
Michael Carakostas, DVM, Ph.D. Date
Consultant
MC Scientific Consulting LLC

_____ _____
Stanley M. Tarka, Jr., Ph.D., Fellow, ATS Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

_____ _____
Thomas Vollmuth, Ph.D. Date
Consultant
Vollmuth and Associates, LLC

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Sternchemie's sunflower lecithin products as ingredients in food products. We unanimously conclude that the intended use of Sternchemie's sunflower lecithin ingredients, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of Sunflower Lecithin for Use in Food", is safe.

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It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

Michael Carakostas, DVM, Ph.D. — Date
Consultant
MC Scientific Consulting LLC

[redacted]

22 January 2020

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS — Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

Thomas Vollmuth, Ph.D. — Date
Consultant
Vollmuth and Associates, LLC

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Sternchemie's sunflower lecithin products as ingredients in food products. We unanimously conclude that the intended use of Sternchemie's sunflower lecithin ingredients, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of Sunflower Lecithin for Use in Food", is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended uses and use levels of the Sternchemie's sunflower lecithin ingredients in foods for human consumption, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in conventional foods specified herein.

It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

Michael Carakostas, DVM, Ph.D.
Consultant
MC Scientific Consulting LLC

Date

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

Date

[redacted]

Thomas Vollmuth, Ph.D.
Consultant
Vollmuth and Associates, LLC

JAN 22, 2020
Date

References

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van Nieuwenhuyzen, W. 2014. The changing worlds of lecithins. International News on Fats, Oils, and Related Materials (INFORM) 25(4).

From:	Don Schmitt
To:	Hice, Stephanie
Cc:	Buxmann, Waldemar; Risley, Chad
Subject:	Re: GRN 000939 - Questions for Notifier
Date:	Thursday, November 5, 2020 9:02:32 AM
Attachments:	image001.png image002.png image003.png Sternchemie FDA Questions and Responses 110520.pdf

Hi Stephanie,

Please find attached Sternchemie's responses to FDA's questions regarding GRN 939; from your email of October 21, 2020.

Best regards,

Don

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

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

From: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Date: Wednesday, October 21, 2020 at 7:38 AM
To: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Subject: Re: GRN 000939 - Questions for Notifier

Good morning Stephanie,

We will have answers to FDA's questions within the 10-day period.

Don

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

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

From: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Date: Wednesday, October 21, 2020 at 7:27 AM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 000939 - Questions for Notifier

Dear Mr. Schmitt,

During our review of GRAS Notice No. 000939, we noted further questions that need to be addressed and are attached to this email.

We respectfully request a response within **10 business days**. If you are unable to complete the response within that time frame, please contact me to discuss further options. Please do not include any confidential information in your response.

If you have questions or need further clarification, please feel free to contact me. Thank you in

advance for your attention to our comments.

Sincerely,

Stephanie Hice

Stephanie Hice, PhD
Staff Fellow (Biologist)
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
stephanie.hice@fda.hhs.gov

Responses to Questions/Comments Regarding GRN 000939:

Question 1. Please clarify if the intended use of sunflower lecithin in milk-based, non-exempt infant formula is (1) as a dietary source of choline, (2) as an emulsifier, dispersing agent, wetting agent and/or release agent or (3) as both.

Response: The intended use of sunflower lecithin in milk-based, non-exempt infant formula is both as a dietary source of choline and as an emulsifier, dispersing agent, wetting agent and/or release agent.

Question 2. Please provide an updated date of submission for the notice (pages 1-2). We note that the notice is dated January 9, 2019, while the provided signature and date in Part 1.10, Signature (page 8) is dated May 18, 2020.

Response: The corrected date on pages 1-2 should read January 9, 2020.

Question 3. On pages 4 and 42, the notifier lists the citation for "Part 7, Supporting Data and Information" as 21 CFR 170.250. The appropriate citation is 21 CFR 170.255. Please provide a statement that corrects this reference.

Response: References to Part 7 on pages 4 and 42 should read 21 CFR 170.255.

Question 4. On page 6, the notifier states that the notified substance 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" (emphasis added). Please note that, per 21 CFR 170.225(c)(6), Part I of the notice should state the notifier's view that the notified substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) based on the notifier's GRAS conclusion. The notifier should provide a statement that sunflower lecithin is exempt from the premarket approval requirements of the FD&C Act based on their conclusion that the notified substance is GRAS under the conditions of its intended use.

Response: The notified substance sunflower lecithin is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) based on Sternchemie's GRAS conclusion. Sunflower lecithin is exempt from the premarket approval requirements of the FD&C Act based on the conclusion that it is GRAS under the conditions of its intended use.

Question 5. On page 6, the abbreviation for SCOGS is indicated as "**Scientific** Committee on GRAS Substances" should be "**Select** Committee on GRAS Substances" as indicated on page 29. Please confirm.

Response: The abbreviation for SCOGS on page 6 should indicate the "**Select** Committee on GRAS Substances" as indicated on page 29.

Question 6. Please clarify if internally developed methods of analysis used for specification parameters have been validated for that particular purpose. If using standard methods, please provide complete and appropriate citations.

Response: Only validated methods of analysis are employed. Please see attachment for an overview of analytical methods.

Question 7. As the intended uses of sunflower lecithin includes use in infant formula, please provide a specification for *Cronobacter sakazakii*, along with the respective analytical methods and results from three non-consecutive batch analyses to demonstrate that sunflower lecithin meets the established specifications.

Response: Three non-consecutive batches of sunflower lecithin are currently being analyzed and the results will be available later in the week of November 2. The results will be forwarded at that time along with a specification and the respective analytical methods employed.

Question 8. On pages 26 and Exhibit 1, page 4, the notifier lists the dates of closure for GRNs 000311 and 000545 as 05/15/2010 and 05/05/2015, respectively. We note that the actual dates of closure for GRNs 000311 and 000545 are 06/15/2010 and 06/05/2015, respectively. For the administrative record, please make a statement that corrects this reference.

Response: On pages 26 and Exhibit 1, page 4, the dates of closure for GRNs 000311 and 000545 should read 06/15/2010 and 06/05/2015, respectively.

Question 9. On pages 26-27, 38-39, and Exhibit 1, page 5, the notifier states "Additional sources for or derivatives of lecithin that have been notified as GRAS to FDA with "no questions letters issued include…phosphatidylserine derived from sunflower lecithin or soy lecithin (GRN 545; FDA, 2015b)". We note that the subject of GRN 000545 does not include phosphatidylserine derived from soy lecithin. For the administrative record, please make a statement that corrects this reference.

Response: We agree that the subject of GRN 000545 does not include phosphatidylserine derived from soy lecithin. Therefore, on pages 26-27, 38-39, and Exhibit 1, page 5, the sentence should read "Additional sources for or derivatives of lecithin that have been notified as GRAS to FDA with "no questions letters issued include…phosphatidylserine derived from sunflower lecithin (GRN 545; FDA, 2015b)".

Question 10. On page 28, the notifier states in a footnote that in their re-evaluation of lecithins, EFSA (2017) Panel did not include infants less than 12 weeks of age. Since the notifier's intended use in milk-based non-exempt infant formula would involve likely consumption by infants less than 12 weeks of age, please provide a brief statement or narrative indicating whether there are safety concerns for infants less than 12 weeks of age.

Response: Given a long history of use of lecithin from a variety of sources (i.e., canola) in infant formula and the safety reviews of national and international organizations and regulatory agencies for its use in infant formula, there are no safety concerns for its use in formula for infants less than 12 weeks of age.

Question 11: On page 31 of the notice, the notifier mentions Gaunt et al. (1967) as the only repeat oral dose toxicity study with lecithin. This reference was not found in the Part §170.250 (References). Please provide this reference.

Response: Gaunt IF, Grasso P, Gangolli SD. 1967. Short-term toxicity study of emulsifier YN in rats. Food and Cosmetics Toxicology 5:623–629.

Question 12: The notifier states on page 32.
"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."

We note that in describing the same study in GRN 000533, its notifier stated that "The Expert Panel has concluded that the 100 mg/kg bw/day level of APGC was 'no observable adverse effect" (NOAEL) level in rats" (page 20 of GRN 000533). The notifier should comment on whether the noted differences in NOAEL of the same study impacts their safety conclusion.

Response: We acknowledge that the notifier of GRN 000533 stated that their expert panel established a NOAEL for that study of 100 mg/kg bw/day. The noted difference in our stated NOAEL as represented by the author vs. that of the GRN 000533 expert panel NOAEL does not impact our safety conclusion.

Question 13: References to "*Salmonella typhimurium*" on page 35-36 should read *Salmonella* Typhimurium. Please make a statement that corrects this reference.

Response: References to "*Salmonella typhimurium*" on page 35-36 should be corrected to read *Salmonella* Typhimurium.

Question 14: In the Report of the Expert Panel, it is stated that existing scientific literature through December 2019 was reviewed. Please provide a statement stating whether an updated literature search through September 2020 identified any new information that would contradict the notifier's GRAS conclusion.

Response: The GRAS notification was first submitted to FDA and received at FDA in early February 2020. In May 2020, following a question raised concerning the use of a specific enzyme (prior to filing of the GRN by FDA), a revised GRN was forwarded to FDA with the requested enzyme-related information and a filing letter received in August 2020. We have conducted an updated literature search through September 2020 and have not identified any new information that would contradict the GRAS conclusion.

Question 15: 3-Monochloropropane-1,2-diol esters (3-MCPDE) are chemical contaminants formed during the refining process of edible oils. Due to their toxicological properties, JECFA established a PMTDI for 3-MCPD and 3-MCPD esters of 4 ug/kg bw/d and EFSA derived a TDI of 2 ug/kg bw/d for 3-MCPD and its esters. The notifier states that sunflower lecithin is produced from sunflower oil via a process that is consistent with that of other edible oils. We note that levels of 3-MCPDE are reported in Appendix A of the notice for batches of sunflower lecithin. Given the stated toxicity concerns and recent efforts to reduce exposure to 3-MCPDE, please provide a narrative that supports the safe use of sunflower lecithin under the intended conditions of use. A discussion of mitigation strategies can be found in the Codex Code of Practice entitled "Reduction of 3-monochloropropane-1,2-diol esters (3-MCPDE) and glycidyl esters (GE) in refined Oil and Food Products Made with Refined Oils" (adopted July 2019, 42nd session, Codex Alimentarius Commission).

Response: The attached Sternchemie statement regarding 3-MCPD in lecithin supports the safe use of the proposed sunflower lecithin product under the intended conditions of use.

Question 16: The dietary exposure to sunflower lecithin for the infant population described in the notice is based on an estimate of formula intake for an infant weighing 10 pounds (approximately 4.5 kg), however, a body weight of 7 kg is used in the calculation of exposure on a body weight basis. Please clarify whether this estimate is representative of average or upper percentile exposure for the consuming infant population and whether the reported 2 - 3 month old age group (i.e., 7 kg body weight) is representative of infants with the highest estimated dietary exposure to sunflower lecithin.

Response: Based on a body weight of 4.5 kg (that is approximately 10 pounds; the lower of the body weight range of 10 -15 pounds) for a 2 - 3 month old infant, the intake of lecithin would range from approximately 1.6 to 4.7 g/kg bw/day. This represents the highest estimated dietary exposure to sunflower lecithin in infants on a body weight basis.

Question 6 Attachment

Overview of chemical analysis methods for lecithins

	Method	
Specification parameter	**DGF**	**AOCS**
Acetone insoluble	DGF F-I 5	Ja 4-46
Toluene insoluble matter	DGF F-I 4c	---
Hexane insoluble matter	---	Ja 3-87
Water (Karl Fischer)	DGF F-I 4	Ja 2b-87
Peroxide Value	DGF F-I 3b	Ja 8-87
Acid Value	DGF F-I 3	Ja 6-55
Gardner Colour	DGFC-IV 4c (10 % Lecithin)	Ja 9-87
Viscosity	DGF F-I 2a	Ja 10-87
Single Phospholipid detection	F-I 6 (HPTLC)	Ja 7-86

Overview of microbiological analysis methods for lecithins

Microbiological Parameter	**Value**	**Unit**	**Method**
Aerobic mesophile micro-organisms	≤ 500	cfu/g	ISO 4833
Yeasts	≤ 50	cfu/g	ISO 21527-2
Moulds	≤ 50	cfu/g	ISO 21527-2
Enterobacteriaceae	≤ 10	cfu/g	ISO 21528-2
Coliforms	≤ 10	cfu/g	ISO 4832
E. coli	negative	in 1 g	ISO 16648-3
Salmonella	negative	in 25 g	ISO 6579
Cronobacter spp. (*Enterobacter sakazakii*)	Negative	In 10 g	ISO/TS 22964 2017-06

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Verwaltungsgesellschaft Arnold Berg mbH
Amtsgericht Hamburg HRB 23039
Geschäftsführer Andreas Reith /
Torsten Wywiol / Volkmar Wywiol

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Konto 951 528
BIC: LAMPDEDD
IBAN: DE65 4802 0151 0000 9515 28

Ust.-ID-Nr.: DE813646864

Question 15 Attachment

Sternchemie
Lipid Technology

Statement on 3-MCPD in Lecithin

Dear Sir or Madam,

The Lecithin products are in compliance with the relevant German and European food legislation, especially – where applicable – with Regulation (EC) No 1881/2006, setting maximum levels for certain contaminants in foodstuffs.

We are analysing 3-MCPD in our lecithin products on a random basis in regular intervals according to our monitoring program.
Based on already performed analyses, we can confirm that the 3-MCPD results have been inconspicuous so far (< 1000 µg/kg).
Kindly note, that there is no binding limit for 3-MCPD in lecithin, set by EU legislation.
Test records are for internal documentation and will not be provided, but can be reviewed within an audit.

For further questions, do not hesitate to contact us.

Quality Management
Sternchemie GmbH & Co. KG

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Fax: + 49 (0) 40 / 284 039-44
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From:	Don Schmitt
To:	Hice, Stephanie
Cc:	Buxmann, Waldemar; Risley, Chad
Subject:	Re: GRN 000939 - Questions for Notifier
Date:	Tuesday, November 17, 2020 1:10:46 PM
Attachments:	image001.png image002.png image008.png image009.png image010.png CERT2020039231[1].pdf CERT2020039083[1].pdf

---

Hi Stephanie,

The *Cronobacter sakazakii* analytical results (subject of FDA Question 7) are attached as promised. Please let me know if the review team has any further questions/needs.

Best regards,

Don

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

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

From: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Date: Thursday, November 5, 2020 at 8:20 AM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Cc: "Buxmann, Waldemar" <wbuxmann@sternchemie.de>, "Risley, Chad" <crisley@berg-schmidt.com>

Subject: RE: GRN 000939 - Questions for Notifier

Dear Mr. Schmitt,

Good morning, and I hope this email finds you well.

Thank you for your attention to our comments. We will let you know if we have any additional questions.

Sincerely,

Stephanie Hice

Stephanie Hice, PhD
Staff Fellow (Biologist)
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
stephanie.hice@fda.hhs.gov

From: Don Schmitt <dschmitt@toxstrategies.com>
Sent: Thursday, November 5, 2020 7:59 AM
To: Hice, Stephanie <Stephanie.Hice@fda.hhs.gov>
Cc: Buxmann, Waldemar <wbuxmann@sternchemie.de>; Risley, Chad <crisley@berg-schmidt.com>
Subject: Re: GRN 000939 - Questions for Notifier

Hi Stephanie,

Please find attached Sternchemie's responses to FDA's questions regarding GRN 939; from your email of October 21, 2020.

Best regards,

Don

Donald F. Schmitt, M.P.H.

Senior Managing Scientist

ToxStrategies, Inc.
739 Thornapple Drive
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phone: 630.352.0303
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Good morning Stephanie,

We will have answers to FDA's questions within the 10-day period.

Don

Donald F. Schmitt, M.P.H.
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To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 000939 - Questions for Notifier

Dear Mr. Schmitt,

During our review of GRAS Notice No. 000939, we noted further questions that need to be addressed and are attached to this email.

We respectfully request a response within **10 business days**. If you are unable to complete the response within that time frame, please contact me to discuss further options. Please do not include any confidential information in your response.

If you have questions or need further clarification, please feel free to contact me. Thank you in advance for your attention to our comments.

Sincerely,

Stephanie Hice

Stephanie Hice, PhD
Staff Fellow (Biologist)
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
stephanie.hice@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

NOFALAB Laboratories

SternChemie GmbH & Co KG
An der Alster 81

20099 Hamburg
Germany

Certificate of Analysis

No. 2020039083

Date of certificate: 17-11-2020

Instruction received on	16-11-2020
Sample received	16-11-2020
Start of laboratory activities	16-11-2020
End of laboratory activities	17-11-2020
Product	Lecithin
Packing	1 Plastic jar
Sample quantity	116 g
Sample temperature	Ambient
Sample sealed	No

Markings

Sample description	LeciStar S200 / Batch: PSC024049-1

Test Results:

Microbiology

qPCR Cronobacter spp	

[redacted]

: 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, as received by NofaLab. This certificate may only be duplicated in total or if authorized by NofaLab in written form. Additional information concerning the perfomance characteristics of this analysis such as measurement uncertainty is available upon request.Interpretations of analysis results stated on this certificate are excluded from our scope of accreditation. All our services are subjected to general conditions applicable as deposited at Chamber of Commerce of Rotterdam, KVK-no.:24361065.

NofaLab B.V.
Jan van Galenstraat 41/51
NL - 3115 JG Schiedam
Phone: +31 10 4279620
Fax: +31 10 4279629
E-mail: customerservice@nofalab.nl

Nofalab is certified by: Gafta

Nofalab is accredited by the council of the federation: FOSFA INTERNATIONAL

Results reported are expressed in product unless clearly stated otherwise.

NOFALAB Laboratories

Certificate No. **2020039083**
Date: 17-11-2020

ANNEX

Sample Determination

Method	**Cronobacter spp qPCR (detection)**
Analysis	qPCR Cronobacter spp per 10 gram
Norm	Equivalent to ISO/TS 22964 (ILRQA 2007LR08091920)
WI	NL/D004
Device	Real time PCR

Sample preparation

Nofalab B.V.
M. Bruggeman
Director

: accredited method (accreditation number L440)

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Nofalab is accredited by the council of the federation:

Results reported are expressed in product unless clearly stated otherwise.

NOFALAB Laboratories

SternChemie GmbH & Co KG
An der Alster 81

20099 Hamburg
Germany

Certificate of Analysis

No. 2020039231

Date of certificate: 17-11-2020

Instruction received on	17-11-2020
Sample received	17-11-2020
Start of laboratory activities	17-11-2020
End of laboratory activities	17-11-2020
Product	Lecithin
Packing	1 Plastic bag
Sample quantity	200 g
Sample temperature	Ambient
Sample sealed	No

Markings

Sample description	LeciStar S200 / PSC024093-1

Test Results:

Microbiology

qPCR Cronobacter spp	

[redacted]

: 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, as received by NofaLab. This certificate may only be duplicated in total or if authorized by NofaLab in written form. Additional information concerning the perfomance characteristics of this analysis such as measurement uncertainty is available upon request.Interpretations of analysis results stated on this certificate are excluded from our scope of accreditation. All our services are subjected to general conditions applicable as deposited at Chamber of Commerce of Rotterdam, KVK-no.:24361065.

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Nofalab is certified by:

Nofalab is accredited by the council of the federation:

Results reported are expressed in product unless clearly stated otherwise.

NOFALAB Laboratories

Certificate No. **2020039231**
Date: 17-11-2020

ANNEX

Sample Determination

Method	**Cronobacter spp qPCR (detection)**
Analysis	qPCR Cronobacter spp per 10 gram
Norm	Equivalent to ISO/TS 22964 (ILRQA 2007LR08091920)
WI	NL/D004
Device	Real time PCR

Sample preparation

Remarks:
The results are derived from certificate number 2020038121.

Nofalab B.V.
M. Bruggeman
Director

: 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, as received by NofaLab. This certificate may only be duplicated in total or if authorized by NofaLab in written form. Additional information concerning the perfomance characteristics of this analysis such as measurement uncertainty is available upon request.Interpretations of analysis results stated on this certificate are excluded from our scope of accreditation. All our services are subjected to general conditions applicable as deposited at Chamber of Commerce of Rotterdam, KVK-no.:24361065.

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Nofalab is certified by: Gafta

Nofalab is accredited by the council of the federation: FOSFA INTERNATIONAL

Results reported are expressed in product unless clearly stated otherwise.

From:	Don Schmitt
To:	Hice, Stephanie
Cc:	"Buxmann, Waldemar"; "Risley, Chad"
Subject:	Re: GRN 000939 - Questions for Notifier
Date:	Thursday, November 19, 2020 2:51:23 PM
Attachments:	image001.png image002.png image008.png image009.png image015.png image016.png image017.png MIB18-10609_eng[2].pdf

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Hi Stephanie,

Here is the third batch of sunflower lecithin analyses for *Cronobacter sakazakii*. As you can see, the COA contains a few other analytical parameters beyond the focus of FDA's question. Sternchemie asks that the other results of this batch (outside that of *Cronobacter sakazakii)* be kept proprietary/confidential if at all possible. Please let me know if that is of concern.

Best regards,

Don

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

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

that

From: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>

Date: Thursday, November 19, 2020 at 12:23 PM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Cc: "'Buxmann, Waldemar'" <wbuxmann@sternchemie.de>, "'Risley, Chad'" <crisley@berg-schmidt.com>
Subject: RE: GRN 000939 - Questions for Notifier

Dear Mr. Schmitt,

Good afternoon, and thank you for your email.

In the notifier's November 5, 2020 response to our questions, the notifier states:

"Three non-consecutive batches of sunflower lecithin are currently being analyzed and the results will be available later in the week of November 2. The results will be forwarded at that time along with a specification and the respective analytical methods employed."

However, it appears as though the results from only two analyses are attached to your November 17, 2020 email. That said, will results from a third analysis be provided?

Thank you again; please let me know if you have any questions.

Sincerely,

Stephanie Hice

Stephanie Hice, PhD
Staff Fellow (Biologist)
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
stephanie.hice@fda.hhs.gov

From: Don Schmitt <dschmitt@toxstrategies.com>
Sent: Tuesday, November 17, 2020 1:06 PM
To: Hice, Stephanie <Stephanie.Hice@fda.hhs.gov>
Cc: Buxmann, Waldemar <wbuxmann@sternchemie.de>; Risley, Chad <crisley@berg-schmidt.com>
Subject: Re: GRN 000939 - Questions for Notifier

Hi Stephanie,

The *Cronobacter sakazakii* analytical results (subject of FDA Question 7) are attached as promised. Please let me know if the review team has any further questions/needs.

Best regards,

Don

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

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

From: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Date: Thursday, November 5, 2020 at 8:20 AM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Cc: "Buxmann, Waldemar" <wbuxmann@sternchemie.de>, "Risley, Chad" <crisley@berg-schmidt.com>
Subject: RE: GRN 000939 - Questions for Notifier

Dear Mr. Schmitt,

Good morning, and I hope this email finds you well.

Thank you for your attention to our comments. We will let you know if we have any additional questions.

Sincerely,

Stephanie Hice

Stephanie Hice, PhD
Staff Fellow (Biologist)
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
stephanie.hice@fda.hhs.gov

From: Don Schmitt <dschmitt@toxstrategies.com>
Sent: Thursday, November 5, 2020 7:59 AM
To: Hice, Stephanie <Stephanie.Hice@fda.hhs.gov>
Cc: Buxmann, Waldemar <wbuxmann@sternchemie.de>; Risley, Chad <crisley@berg-schmidt.com>
Subject: Re: GRN 000939 - Questions for Notifier

Hi Stephanie,

Please find attached Sternchemie's responses to FDA's questions regarding GRN 939; from your email of October 21, 2020.

Best regards,

Don

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

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

From: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Date: Wednesday, October 21, 2020 at 7:38 AM
To: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Subject: Re: GRN 000939 - Questions for Notifier

Good morning Stephanie,

We will have answers to FDA's questions within the 10-day period.

Don

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

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From: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Date: Wednesday, October 21, 2020 at 7:27 AM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 000939 - Questions for Notifier

Dear Mr. Schmitt,

During our review of GRAS Notice No. 000939, we noted further questions that need to be addressed and are attached to this email.

We respectfully request a response within **10 business days**. If you are unable to complete the response within that time frame, please contact me to discuss further options. Please do not include any confidential information in your response.

If you have questions or need further clarification, please feel free to contact me. Thank you in advance for your attention to our comments.

Sincerely,

Stephanie Hice

Stephanie Hice, PhD
Staff Fellow (Biologist)
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Phone +49 471 4832 340
Fax +49 471 4832 341

info@impetus-bioscience.de
www.impetus-bioscience.de

Your order from 07.12.2018

Bremerhaven, 24.12.2018

Certificate of Analysis

Sample designation:	LeciStar S 100
Your sample number:	PSC020733
Our sample number:	MIB18-10609
Date of receipt:	18.12.2018
Temperature of receipt:	Room temperature
Sample description/packaging:	Sample in a plastic container
Batch/Coding/sell-by date:	
Sample amount:	2.205,00 g
Sample preparation:	Mibio
Start of analysis:	18.12.2018
End of analysis:	24.12.2018

Microbiological analyses

Parameter	Result	Comment	Analysis mode (method)
Cronobacter spp. (Enterobacter sakazakii)	negative in 10 g		Qualitative RealTime PCR analysis according to L-008 S-064 2017-12 following ISO/TS 22964 2017-06

Microbiological analyses

Parameter	Result	Comment	Analysis mode (method)

Remarks

The results exclusively refer to the analysed proportion of the sample we have received from you. They do not necessarily have to be representative for the product from which the sample was taken.
It is not allowed to publish this certificate whole or in part without prior consent from the laboratory. Our general terms of business are considered as accepted.

Jan-Christoph Schwarze
Technical Management
Impetus GmbH & Co. Bioscience KG

This certificate and the signature have been drawn up electronically.
The original will be sent on request.

From:	Don Schmitt
To:	Hice, Stephanie
Cc:	Buxmann, Waldemar; Risley, Chad
Subject:	Re: GRN 000939 - Questions for Notifier
Date:	Monday, December 21, 2020 8:33:58 AM
Attachments:	image001.png image002.png image003.png Sternchemie Responses GRN939 122120.docx

Hi Stephanie,

Attached are Sternchemie's responses to FDA's latest questions regarding GRN 939.

Don

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

ToxStrategies, Inc.
739 Thornapple Drive
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email: dschmitt@toxstrategies.com

From: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Date: Thursday, December 10, 2020 at 8:03 AM
To: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Subject: Re: GRN 000939 - Questions for Notifier

Hi Stephanie,

We will have answers to your questions in the requested 10-day period.

Don

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

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

From: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Date: Wednesday, December 9, 2020 at 3:11 PM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: RE: GRN 000939 - Questions for Notifier

Dear Mr. Schmitt,

During our review of GRAS Notice No. 000939, we noted further questions that need to be addressed and are attached to this email.

We respectfully request a response within **10 business days**. If you are unable to complete the response within that time frame, please contact me to discuss further options. Please do not include any confidential information in your response.

If you have questions or need further clarification, please feel free to contact me. Thank you in advance for your attention to our comments.

Sincerely,

Stephanie Hice

Stephanie Hice, PhD
Staff Fellow (Biologist)
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
stephanie.hice@fda.hhs.gov

Responses to FDA Questions/Comments Regarding GRN 000939 (December 9, 2020):

Question 1. Please provide an estimate of maximum potential dietary exposure to 3-MCPD (in µg/kg bw/d) from the consumption of sunflower lecithin under the intended conditions of use. A comparison of the notifier's estimate to the JECFA's Provisional Maximum Tolerable Daily Intake would serve a more solid basis for their safety conclusion.

Question 2. On page 67 of the notice (Certificate of Analysis No. 2019043829), the sum of 3-MCPD and Glycidyl ester is indicated as 95 ppb. Please confirm that, based on the notifier's use level and intended conditions of use in milk-based non-exempt infant formula for term infants, the levels of glycidyl fatty acid esters expressed as glycidol are below the maximum level of 6 ppb in liquid infant formula as expressed in section 4.2.4 of Regulation (EC) No 2018/290.

Responses:

Occurrence and Levels of 3-MCPD in Sunflower Lecithin

Sunflower lecithin is produced from raw sunflower oil via a process that is consistent with that of other edible oils. Lecithin is separated from the oil at an early stage in the so-called degumming process by passing water through the oil to precipitate out gums.

3-monochloropropane-1,2-diol esters (3-MCPDE) and glycidyl esters (GE) are contaminants that can occur in edible oils and are typically formed during industrial refining, when the oils are heated at very high temperatures to remove unwanted tastes, colors, or odors. These critical refining steps only take place after degumming, that is when the lecithin has already been separated from the oil.

It is known that other factors might affect the likelihood of oils to form 3-MCPDE and GE during refining—including climate, soil, and growth conditions of oil-producing plants, plant genotype, and harvesting techniques.

Still, the content of 3-MCPD and GE in raw vegetable oils – that is the source of lecithin production – is very low. Accordingly, Sternchemie tests for 3-MCPDE and GE levels on a biannual base within the standard monitoring program:

Over the last 5 years, 3-MCPD and GE levels in sunflower lecithin have typically tested at or below the detection limit of 50 or 100 µg/kg, respectively. Only two samples have been tested above 100 µg/kg, but at 166 µg/kg and 244 µg/kg in the year 2016.

Intended Use and Intake Assessment

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 liquid formula per day (1 ounce equals 28.3 grams); equivalent to approximately 700 grams of liquid formula per day, or 108 grams of powdered formula based on a recommended dilution of 1:6.5, respectively.

Based on the proposed average and maximum incorporation of lecithin in powdered infant formula of approximately 1 to 3 g/100 g (similar to use levels of canola lecithin in GRN 533), intake of lecithin would range from 1.1 to 3.2 g/day or 0.2 to 0.7 g/kg bw/day for an infant 2 to 3 months of age weighing approximately 4.5 kg. This represents the highest estimated dietary exposure to sunflower lecithin in infants on a body weight basis.

JECFA established a PMTDI for 3-MCPD and 3-MCPD esters of 4 µg/kg bw/day and EFSA derived a TDI of 2 µg/kg bw/day for 3-MCPD and its esters. At the highest concentration level of 3-MCPD seen in sunflower lecithin so far (244 µ/kg), an exposure of 0.7 g of sunflower lecithin/kg bw/day would translate into an amount of 0.17 µg of 3-MCPD/kg bw/day, that is a factor of 20x below the PMTDI established by JECFA, and more than 10x lower than the TDI established by EFSA.

(*) Please be informed that there was calculation error in our original submission. While the incorporation rate of lecithin in infant formula was referring to the powdered formula, the calculation of intake was based on the liquid formula, that is a 1:6.5 dilution. Accordingly, intake levels had been overestimated and are herewith corrected.