AIBMR Life Sciences, Inc.

January 28, 2020

Susan Carlson, PhD
Division Director
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
5001 Campus Drive
College Park, MD 20740

Dear Dr. Carlson:

In accordance with regulation 21 CFR Part 170 Subpart E (Generally Recognized as Safe (GRAS) Notice), on behalf of *Société d'Exploitation de Produits pour les Industries Chimiques* (hereinafter called SEPPIC) (the notifier), the undersigned, Kayla Preece, submits, for FDA review, the enclosed notice that Ceramosides™ Oil Neutra is GRAS for use in foods.

Should you have any questions or concerns regarding this notice, please contact me at 253-286-2888 or kayla@aibmr.com.

Sincerely,

Kayla Preece, ND (agent of the notifier)
Research and Regulatory Consultant
AIBMR Life Sciences, Inc. ("AIBMR")

#907

Notice to US Food and Drug Administration of the Conclusion that the Intended Use of Ceramosides™ Oil Neutra is Generally Recognized as Safe

Submitted by the Notifier:

SEPPIC – Air Liquide Healthcare
Specialty Ingredients
50 boulevard National
CS 90020
92257 La Garenne Colombes Cedex, France
and
E.P.I. France
3 rue de Préaux,
02130 Villers-sur-Fère, France

Prepared by the Agent of the Notifier:

AIBMR Life Sciences, Inc
2800 E. Madison Street, Suite 202
Seattle WA 98112

January 28, 2020

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Part 1: Signed Statements and Certification

1.1 Submission of GRAS Notice

Société d'Exploitation de Produits pour les Industries Chimiques (hereinafter called SEPPIC) (the notifier) is submitting a new GRAS notice in accordance with 21 CFR Part 170, Subpart E, regarding the conclusion that Ceramosides™ Oil Neutra is Generally Recognized as Safe (GRAS) for its intended use, consistent with section 201(s) of the Federal Food, Drug and Cosmetic Act.

1.2 Name and Address of the Notifier and Agent of the Notifier

Notifier

Marie-Anne Milesi
Nutrition Regulatory Affairs Manager
Société d'Exploitation de Produits pour les Industries Chimiques (SEPPIC S.A.),
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For E.P.I France, 3 rue de Préaux, 02130 Villers-sur-Fère, France

Agent of the Notifier

Kayla Preece
Scientific and Regulatory Consultant
AIBMR Life Sciences, Inc.
2800 E. Madison Street, Suite 202
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Tel: (253) 286-2888
kayla@aibmr.com

1.3 Name of the Substance

Wheat seed oil (Ceramosides™ Oil Neutra)

1.4 Intended Conditions of Use

Ceramosides™ Oil Neutra is intended to be used as an ingredient in the various food categories detailed in Part 3 of this report. Addition levels will range from 0.2–24 mg/g, depending on the food category. Ceramosides™ Oil Neutra is not intended

for use in foods where standards of identity would preclude such use, such as infant formula, or any products that would require additional regulatory review by the United States Department of Agriculture (USDA).

1.5 Statutory Basis for GRAS Conclusion

The conclusion of GRAS status of Ceramosides™ Oil Neutra for its intended conditions of use, stated in Part 1.4 of this notice, has been made based on scientific procedures.

1.6 Not Subject to Premarket approval

We have concluded that Ceramosides™ Oil Neutra is GRAS for its intended conditions of use, stated in Part 1.4 of this notice, and, therefore, such use of Ceramosides™ Oil Neutra is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act.

1.7 Data and Information Availability Statement

The data and information that serve as the basis for this GRAS conclusion will be available for review and copying during customary business hours at the office of *Société d'Exploitation de Produits pour les Industries Chimiques*, Paris La Défense - 50 boulevard National - CS 90020 - 92257 La Garenne Colombes Cedex – France, Telephone: +33 1 42 91 41 34, email: marie-anne.milesi@airliquide.com or will be sent to FDA upon request.

1.8 Exemption from Disclosure under the Freedom of Information Act

None of the data and information in Parts 2 through 7 of this GRAS notice are considered exempt from disclosure under the Freedom of Information Act (FOIA) as trade secret or commercial or financial information that is privileged or confidential.

1.9 Certification of Completion

We hereby certify that, to the best of our knowledge, this GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of the safety and GRAS status of the use of Ceramosides™ Oil Neutra.

2020-01-28

Marie-Anne Milesi
Nutrition Regulatory Affairs Manager
Notifier

Date

Part 2: Identity, Manufacture, Specifications, and Physical or Technical Effect

2.1 Identification

Ceramosides™ Oil Neutra is derived from the seed of wheat (*Triticum aestivum*). Taxonomic basonyms include *Triticum sativum* and *Triticum vulgare*. The product is made from purified wheat flour that is extracted with ethanol to isolate the specific fraction that is rich in polar lipids. The result of this process is an oil consisting of not less than 95% wheat lipids.

2.1.1 Source Material

Wheat lipids represent a minor fraction of the whole plant grain (from 1.5–2.5%).[1] The most abundant nonpolar lipids contained in flour are triacylglycerols (i.e. triglycerides or TAGs) and free fatty acids (FFAs), while the polar lipid fraction is composed of glycolipids, phospholipids, and sphingolipids (see Figure 1). The major fatty acids present in wheat grain have been reported as linoleic acid (56.3%), palmitic acid (24.5%), oleic acid (11.5%), linolenic acid (3.7%), and stearic acid (1.0%).[2] The glycolipids contained in wheat consist primarily of monogalactosyldiacylglycerol (MGDG) and digalactosyldiacylglycerol (DGDG) while the prominent phospholipids are *N*-acyl phosphatidylethanolamine (NAPE), phosophatidylethanolamine (PE), and phosphatidylcholine (PC). Other phospholipids present include phosphatidylinositol (PI) and phosphatidylserine (PS).[1] The sphingoid base, or amino alcohol base, is common to all sphingolipids, and replaces the glycerol backbone found commonly in other lipids.[3] Sphingolipids can be found as ceramides, glycolipids such as cerebrosides and gangliosides, and phospholipids such as sphingomyelin. Ceramides (the simplest sphingolipids) are composed of a sphingoid base coupled with a fatty acid by an amine link between the NH_2 functional group of the sphingoid base and the acyl group of fatty acids. Cerebrosides are glycolipids consisting of a ceramide plus a carbohydrate (sugar) moiety, while gangliosides are more complex sphingo-glycolipids. According to the origin (plant, animal, yeast or bacteria) of the sphingolipids, the sphingoid moiety can vary.[4 5]

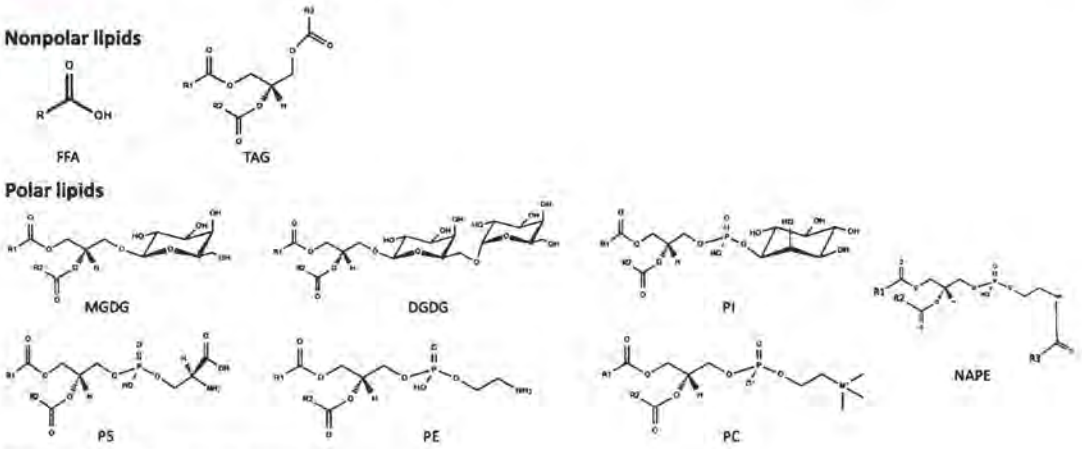

Figure 1. Wheat Lipids[1]

FFA: free fatty acids, TAG: triacylglycerol, MGDG: monogalactosyldiacylglycerol, DGDG: digalactosyldiacylglyerol, PI: Phosphatidylinositol, PS: phosphatidylserine, PE: phosphatidylethanolamine, PC: phosphatidylcholine, NAPE: n-acyl phosphatidylethanolamine.

2.1.2 Ceramosides™

Ceramosides™ Oil Neutra is a viscous light brown to brown oil with a characteristic cereal odor. The polar lipid fraction comprises ≥ 30% of the total lipid content of the ingredient and, in terms of total ingredient mass, consists of ≥ 15% sphingolipids, ≥ 15% DGDG, and ≤ 10% phospholipids. SEPPIC deduces that the remaining 60–70% fraction of the total lipid content is comprised of TAGs based on the composition of wheat lipids (see Table 1).

Qualitative analysis provided by SEPPIC demonstrates that other minor components of the polar lipid fractions include MGDG and glycosylated sterols. The predominant sphingolipids have been determined to be palmitoleoyl phytosphingosine, oleoyl sphingosine, and linoleoyl phytosphingosine while the sugar moiety in each case is allose (see Figure 2). A typical fatty acid composition of Ceramosides™ Oil Neutra is shown in Table 2 which is the mean analysis of three random batches of oil.

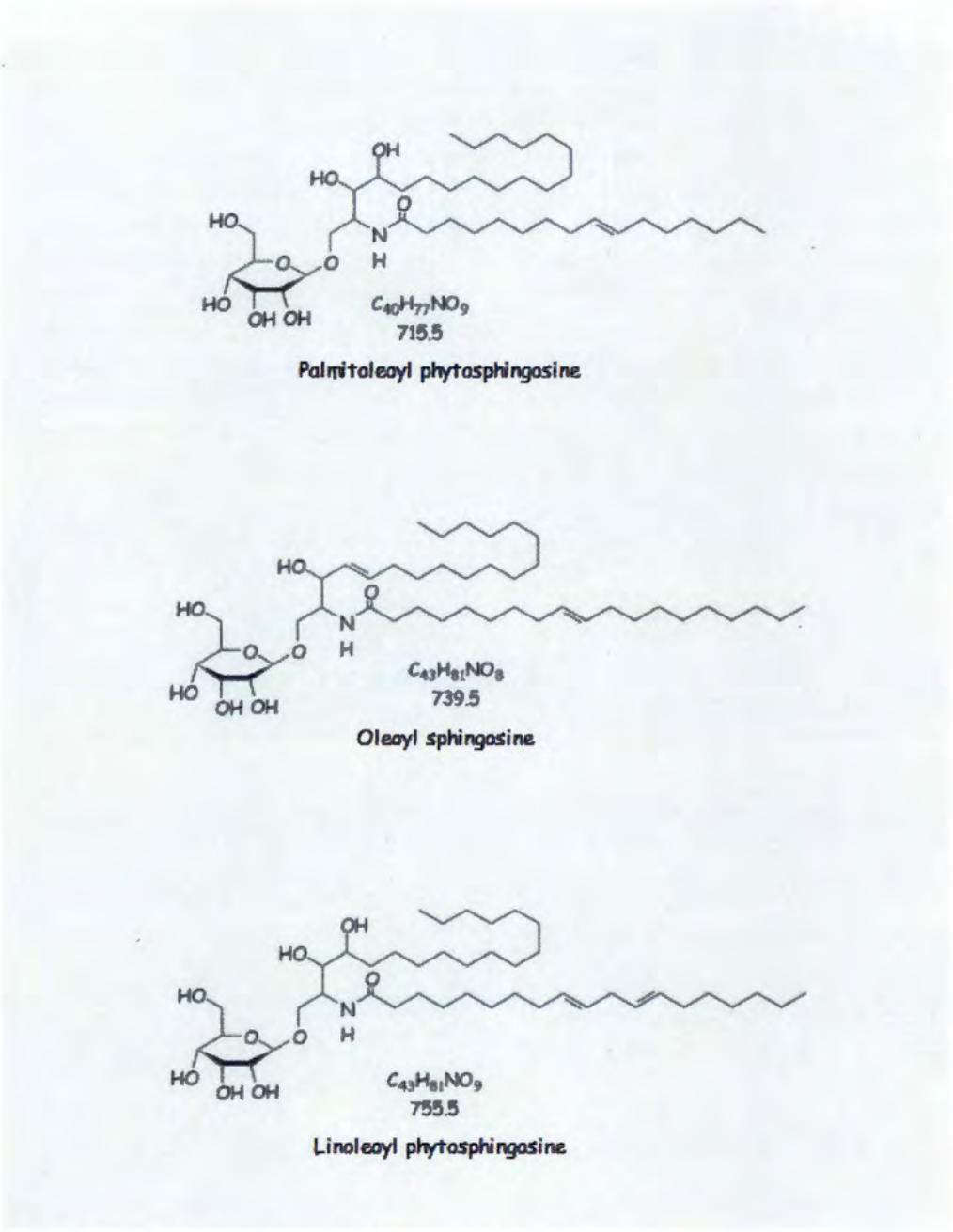

Figure 2. Ceramides Found in Ceramosides™ Oil Neutra

Table 1. Approximate Composition of Ceramosides™ Oil Neutra

Ingredient	Content
Sphingolipids	15 %
DGDG	15 %
Phospholipids	10 %
Triglycerides	60 %

Table 2. Typical Fatty Acid Profiles of Ceramosides™ Oil Neutra

Fatty Acids		Ceramosides™ Oil Neutra (g/100 g of total fatty acids)
Common Name	Lipid numbers + Δ^X	
Myristic	C14:0	0.02 ± 0.04
Pentadecanoic	C15:0	0.08 ± 0.04
Palmitic	C16:0	19.96 ± 0.22
Palmitoleic	C16:1, *cis*-Δ^9	0.20 ± 0.00
Margaric	C17:0	0.20 ± 0.00
Heptadecenoic	C16:1, *cis*-Δ^{10}	0.08 ± 0.04
Stearic	C18:0	0.88 ± 0.08
Oleic	C18:1, *cis*-Δ^9	7.68 ± 0.20
Linoleic	C18:2, all-*cis*-$\Delta^{9, 12}$	66.56 ± 0.38
Alpha-linolenic	C18:3, all-*cis*-$\Delta^{9, 12, 15}$	3.52 ± 0.04
Arachidic	C20:0	0.02 ± 0.04
Gadoleic	C20:1, *cis*-Δ^9	0.20 ± 0.00
Eicosadienoic	C20:2, all-*cis*-$\Delta^{11, 14}$	0.10 ± 0.00
Behenic	C22:0	0.24 ± 0.05
Erucic	C22:1, *cis*-Δ^{13}	0.00 ± 0.00
Docosahexaenoic	C22:6, all-*cis*- $\Delta^{4, 7, 10, 13, 16, 19}$	0.00 ± 0.00
Tricosanoic	C23:0	0.00 ± 0.00
Lignoceric	C24:0	0.24 ± 0.09
Nervonic	C24:1, *cis*-Δ^{15}	0.06 ± 0.05

2.2 Manufacturing

2.2.1 Manufacturing Overview

Wheat lipid extraction: Wheat flour fraction is incorporated into ethanol under mechanical stirring in a stainless-steel tank, and the extraction is performed for a specified period of time (see Figure 3).

Filtration (solid/liquid separation): Solid particles are separated from the liquid fraction by filtration under vacuum in an appropriate container. The filtrate obtained contains the lipids and the solvent (ethanol).

Concentration and purification of wheat lipids: The lipids contained in the filtrate are concentrated by evaporation of ethanol under vacuum. The product obtained at this step is a wheat oil composed of triglycerides and polar lipids (sphingolipids, digalactosyldiglycerides, and phospholipids).

Packaging: Ceramosides™ Oil Neutra is conditioned into 5 kg HDPE drums compatible for food content. Each batch is controlled to validate conformity to specifications.

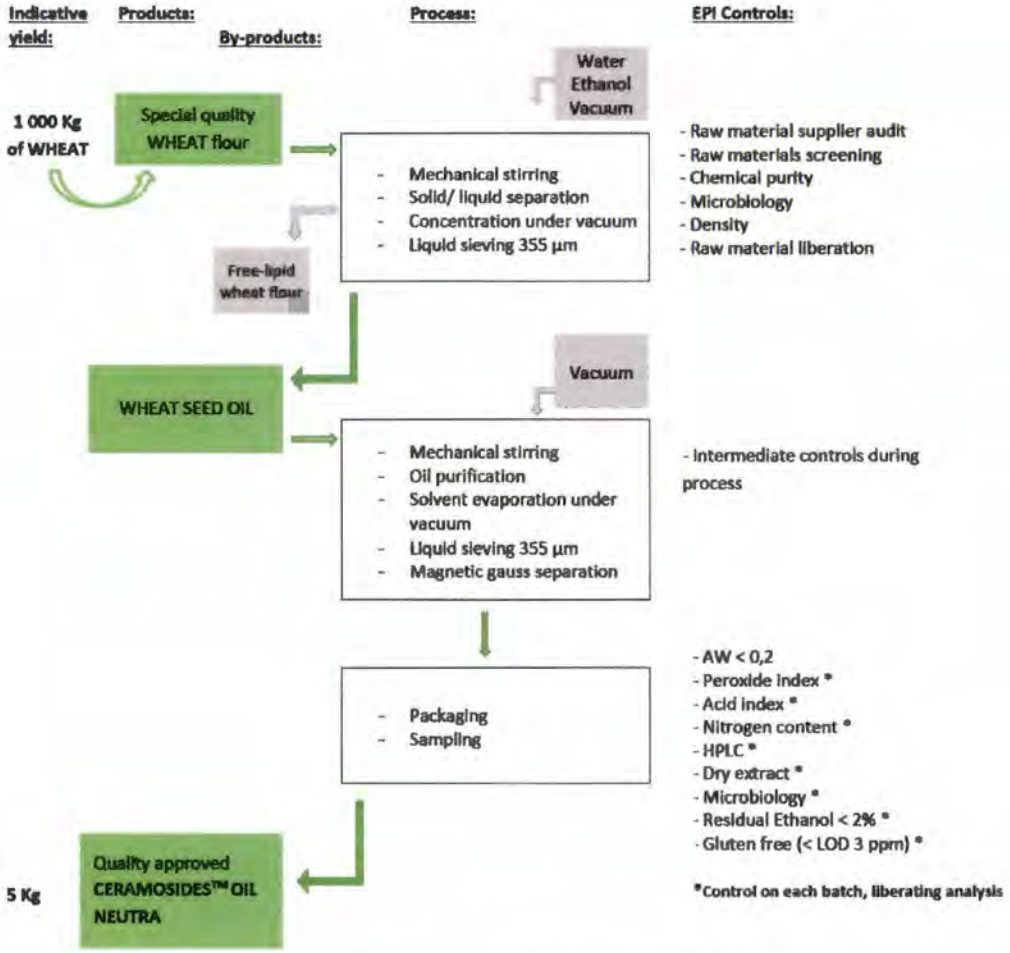

Figure 3. Manufacturing Flowchart Ceramosides™ Oil Neutra

2.2.2 Good Manufacturing Practice

Ceramosides™ Oil Neutra from SEPPIC is manufactured according to Good Manufacturing Practices (GMP) equivalent practices by EPI France Sarl, in an FDA registered facility (N° 19310227934) under a patented (France) Hazard Analysis

Critical Control Point (HACCP) food grade process. SEPPIC requires suppliers to provide data, accreditations, certificates, and assays for purposes of verifying that their raw materials conform to currently enforceable EU food regulations for general food legislation, food hygiene, contaminants, and pesticides.

2.2.3 Raw Materials

Raw materials used in the production of Ceramosides™ Oil Neutra are of appropriate food grade.

2.3 Specifications

The specifications for the food-grade product Ceramosides™ Oil Neutra, along with the specification methods, are listed in Table 3.

Table 3. Ceramosides™ Oil Neutra Specifications

Test Items	Specification	Method
Marker Compounds		
Total sphingolipids including glycosphingolipids	≥ 15%	IM 06520-V3 (indirect[1])
DGDG	≥ 15%	IM 06522-V4 (RP-HPLC, ELSD)
Total Nitrogen linked with polar lipids	≥ 0.20%	IM adapted from Dumas (combustion) NF EN ISO 16634-1-12/2008
Polar Lipids Identification[2]	Identical to assay	IM 06223-V3 (TLC)
Physical Characteristics		
Aspect	Viscous oil	Visual and Olfactive
Color	Brown to light brown	
Odor	Cereal characteristic	
Chemical Data		
Acid Value	< 20 mg KOH/g	NF EN ISO 660-09/2009
Peroxide Value	< 10 mEq/kg	NF EN ISO 3960-06/2010
Density[2]	1.000± 0.030	IM 06224[3]
Humidity	< 5%	NF EN ISO 662-02/2001
Dry Extract	> 95%	NF EN ISO 662-02/2001
Microbiological Tests		
Total aerobic plate count	≤ 100 cfu/g	NF EN ISO 4833-1-10/2013
Total Yeast & Mold	≤ 100 cfu/g	NF V08-036-05/2003
Enterobacteria	Absent/g	NF ISO 21528.1-12/2014

Staphylococci coagulase + (37°C) including *Staphylococcus aureus*	Absent/g	NF EN ISO 6888.3-06/2003
Escherichia coli	Absent/g	Internal MA 104.4 adapted from ISO16649.3
Salmonella	Absent/10 g	BRD 07/11-12/05
Listeria monocytogenes[2]	Absent/25 g	ALOA-AES 10/3-09/00
Allergens		
Residual gluten	< 20 ppm	Internal Ridaquick Gliadine kit (R-Biopharm AG) test
Residual gluten[2]	< 20 ppm	AOAC-OMA 2012.01

Abbreviations: ALOA-AES, Proprietary Agar for testing Listeria developed by AES Chemunex; AOAC, Association of Official Agricultural Chemists; BRD, Bio-Rad; cfu, colony forming units; EN, European norm; ELSD, Evaporating light scattering detector; HS, Head Space; IM, Internal Method; ISO, International Organization for Standardization; MA, Adapted method; NF, French norm; NF V, French norm for food industry; OMA, Official Method of Analysis; RP-HPLC, reverse phase high performance liquid chromatography; TLC, thin layer chromatography

[1] Calculation based upon total nitrogen content.

[2] Analysis guaranteed under statistical control: minimum once a year.

[3] Calculation based on the determination of volumic weight at 20°C

2.3.1 Batch Analysis

Production conformity and consistency of Ceramosides™ Oil Neutra are tested in production lots (see Table 4).

Table 4. Ceramosides™ Oil Neutra Batch Analyses

Test Items	Specification	Lot # 411171219 Manufactured 12/16/2017	Lot # 411190718 Manufactured 07/18/2019	Method
Marker Compounds				
Total sphingolipids including glyco-sphingolipids	≥ 15%	27.6%	18.3%	IM 06520-V3 (indirect[1])
DGDG	≥ 15%	15.6%	23.0%	IM 06522-V4 (RP-HPLC, ELSD)
Total Nitrogen linked with polar lipids	≥ 0.2%	0.36%	0.34%	IM adapted from Dumas (combustion) NF EN ISO 16634-1-12/2008

Polar Lipids Identification[2]	Identical to assay	Conforms	Conforms	IM 06223-V3 (TLC)
Physical Characteristics				
Aspect	Viscous oil	Conforms	Conforms	Visual and olfactive
Color	Brown to light brown	Conforms	Conforms	
Odor	Cereal characteristic	Conforms	Conforms	
Chemical Tests				
Acid Value	< 20 mg KOH/g	11.6 mg KOH/g	11.6 mg KOH/g	NF ISO 660-09/2009
Peroxide Value	< 10 mEq/kg	< 0.1 mEq/kg	2.6 mEq/kg	NF ISO 3960-06/2010
Density[2]	1.000± 0.030	Conforms	Conforms	IM 06224[3]
Loss on drying	< 5%	1.7%	0.7%	NF EN ISO 662-02/2001
Dry Extract	> 95%	98.3%	99.3%	NF EN ISO 662-02/2001
Microbiological Tests				
Total Aerobic Microbial	≤ 100 cfu/g	<10 cfu/g	<10 cfu/g	NF EN ISO 4833-1-10/2013
Total Yeast & Mold	≤ 100 cfu/g	<10 cfu/g	<10 cfu/g	NF V08-036-05/2003
Enterobacteria	Absent/g	Absent/g	Absent/g	NF ISO 21528.1-12/2014
Staphylococci coagulase + (37°C) including *Staphylococcus aureus*	Absent/g	Absent/g	Absent/g	NF ISO 6888.3-06/2003
Escherichia coli	Absent/g	Absent/g	Absent/g	Internal MA.104.4 adapted from ISO16649.3
Salmonella	Absent/10 g	Absent/10 g	Absent/10 g	BRD 07/11-12/05
Listeria monocytogenes[2]	Absent/25 g	Absent/25 g	Absent/25 g	ALOA-AES 10/3- 09/00
Allergens				
Residual gluten	< 20 ppm	Conforms	Conforms	Internal Ridaquick Gliadine kit (R-Biopharm AG) test
Residual gluten[2]	< 20 ppm	Conforms	Conforms	AOAC-OMA 2012.01

Abbreviations: ALOA-AES, Proprietary Agar for testing Listeria developed by AES Chemunex; AOAC, Association of Official Agricultural Chemists; BRD, Bio-Rad; cfu, colony forming units; EN, European norm; ELSD, Evaporating light scattering detector; HS, Head Space; IM, Internal Method; ISO, International Organization for Standardization; MA, Adapted method; n/a, not applicable; NF, French norm; NF V, French norm for food industry; OMA, Official

Method of Analysis; RP-HPLC, reverse phase high performance liquid chromatography; TLC, thin layer chromatography
[1] Calculation based upon total nitrogen content.
[2] Analysis guaranteed under statistical control: minimum once a year.
[3] Calculation based on the determination of volumic weight at 20°C

2.3.2 Heavy Metal Analysis

Heavy metal analysis for the product is in compliance with European regulation (EC) N° 1881/2006 on the finished product and on the wheat raw material used for manufacturing. As SEPPIC has never received a positive heavy metal test result in over 10 years, they now schedule individual heavy metal frequency testing to occur once a year. While the product has been manufactured for many years, specifications have recently changed to include a new methodology and decreased specification limits. As a result, only the two batches noted in Table 4 have been tested thus to conform with the updated specifications as listed in Table 5.

Table 5. Ceramosides™ Oil Neutra Heavy Metal Specification

Test Items	Specification	Method
Arsenic	≤ 0.1 ppm	IM adapted from NF EN 15763 (ICP-MS)
Cadmium	≤ 0.1 ppm	
Lead	≤ 0.2 ppm	
Mercury	≤ 0.1 ppm	

Abbreviations: EN, European norm; ICP-MS, Inductively coupled plasma mass spectrometry; IM, Internal Method; NF, French norm.

2.3.3 Residual Solvent Analysis

Ethanol is a class 3 solvent used in the manufacturing of Ceramosides™ Oil Neutra. Analyses are performed on each batch guaranteeing Ceramosides™ Oil Neutra contains < 9000 ppm of ethanol. Based on intended use and exposure estimates calculated in Part 3, solvent exposures meet International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) guidelines.

2.3.4 Mycotoxins, Aflatoxins and Residual Pesticide Analysis

E.P.I. France's plan for contaminant control is based on risk analysis (HACCP) and Food Safety Plan (FSMA US regulation). Based on this risk analysis, they have established that the raw material is tested once per year on one batch and finished products are tested once per year on one batch per grade respectively for mycotoxins, aflatoxins and residual pesticides.

2.3.5 Shelf-Life Stability

A three-year shelf-life from the time of manufacture has been recommended as an appropriate expiration period for Ceramosides™ Oil Neutra. This recommendation is based upon 36-month long-term stability tests of lot numbers 11070529 and 11070615. The long-term stability tests were conducted at 15–25°C and 65–85% relative humidity under conditions of commercial packaging. Commercial packaging is a closed PEHD flask.

The stability study demonstrates adequate stability along with an extended shelf-life two to four months beyond the three-year recommendation. All physical and chemical parameters were stable, and all active components composed of wheat lipids including glycosyl ceramides and DGDG were preserved with no traces of peroxidation.

2.4 Physical or Technical Effect

Ceramosides™ Oil Neutra is not intended to produce any physical or other technical effects that is relevant to the safety of the ingredient.

Part 3: Dietary Exposure

3.1 Intended Use

Ceramosides™ Oil Neutra is intended to be used as an ingredient in the food categories and at the addition levels shown in Table 6. Ceramosides™ Oil Neutra is not intended for use in infant formula, meat, poultry, egg, catfish, or any products that would require additional regulatory review by USDA.

Table 6. Ceramosides™ Oil Neutra Intended Uses

Food Category	Maximum Intended Addition Level (mg/g)
	Oil Neutra
Bars	2
Chewing gums	24
Biscuits	10
Fruit juices, excluding citrus	0.3
Coffee	0.2
Tea	0.2
Fruit drinks	0.3
Other functional beverages	0.2
Gelatin desserts or salads	0.6
Candies	3
Ready to eat cereals	10
Milk, fluid, imitation	0.3
Yogurt	0.5
Flavored milk and milk drinks, fluid	0.3

3.2 Exposure Estimates

Exposure to Ceramosides™ Oil Neutra from the intended use categories was estimated for the U.S. population using food consumption data from the What We Eat in America (WWEIA) dietary component of the National Health and Nutrition Examination Surveys (NHANES). The NHANES 2013–2014 data were analyzed using Creme Food Safety software 3.6 (www.cremeglobal.com). These data were obtained from 7574 individuals who underwent two non-consecutive 24-hour dietary recall interviews (the first was collected in-person, the second by phone 3–10 days later).

WWEIA food codes that were considered most similar to the intended use categories were utilized in the assessment and were assigned the relevant intended use concentrations. Creme software is a probabilistic modeling tool that uses high-performance computing to predict intake (including total aggregate exposure) of

food groups and/or individual food ingredients. Creme Food Safety performs calculations using large-scale food consumption data sets. It bases the calculated estimates on each individual's body weight from the survey, as opposed to averaged body weights. Calculations also incorporated the NHANES assigned sample weights for each individual in the survey, which measure the number of people in the population represented by that specific subject and help to ensure that the results statistically represent the entire U.S. population. Sample weights for NHANES participants incorporate adjustments for unequal selection probabilities and certain types of non-response, as well as an adjustment to independent estimates of population sizes for specific age, sex, and race/ethnicity categories. The data are shown for "food consumers" (which includes only data from individuals who reported consuming one or more food/beverage categories intended to contain the Ceramosides™ Oil Neutra over the two-day survey period, as opposed to the whole population). Results are given as both absolute exposure (mg/day), as well as exposure relative to body weight (mg/kg bw/day).

The relative standard error (RSE; calculated by dividing the standard error of the estimate by the estimate itself and multiplying by 100) is a statistical criterion that can be used to determine the reliability of estimates as pertains to the population (the larger the RSE the less reliable the estimate).[6] RSE values greater than 25–30% are often considered reasonable cut-offs by which to consider a value unreliable.[6, 7] For the purpose of this GRAS conclusion, an RSE value of greater than 25% was used to indicate that the estimated value was unreliable with regard to representing the population. RSE values are shown for the 90th percentile values only, as the 90th percentile values are the most pertinent for the exposure estimates. All of the values were considered reasonably reliable using the 25% cut-off.

Data estimated directly from the NHANES short 2-day survey do not necessarily adequately represent individual usual long-term intake due to the large amount of random error. This is because it may not correctly capture infrequent consumers. It assumes that subjects who consumed a product on a survey day consume it every day of the year, and it does not adjust for potential day-to-day variation in intake (i.e., intra-individual variation over time is not accounted for). Thus estimation of "usual" or "lifetime" exposure was also added to the model based on methodologies developed by Nusser et al., 1996, at Iowa State University.[8] These lifetime data are considered the most relevant data, as GRAS exposure estimates should be based on expected regular exposure over the lifespan. The technique of estimating usual/lifetime intakes relies on the ability to transform the input daily average data (from food consumers) into normality, which is tested using the Anderson-Darling test statistic within the Creme Global software.

The Ceramosides™ Oil Neutra exposure estimates from the intended use categories are shown for the total population (ages 2 years and older) below in Tables 7 and 8.

Table 7. Total (Aggregate) Absolute Exposure to Ceramosides™ Oil Neutra by Proposed Use Food Consumers Using NHANES 2013–14 Data (mg/day)

Total Population (ages 2+)	N	% of total pop	Absolute Consumption Daily Average (mg/day)				90th% RSE Value	Lifetime 90th% Exposure Estimates (mg/day)
			Mean	Mean std err	90th%	90th% std err		
Oil Neutra	6691	94.9	3122.4	54.7	6661.8	131.8	2.0	5268.3*

Creme runs #397
*Creme warning -2048, "Number of days per person should be constant for a Foods calculation" (data may still be used)

Table 8. Total (Aggregate) Exposure to Ceramosides™ Oil Neutra by Proposed Use Food Consumers Relative to Body Weight Using NHANES 2013–14 Data (mg/kg bw/day)

Total Population (ages 2+)	N	% of total pop	Consumption Relative to Body Weight Daily Average (mg/kg bw/day)				90th% RSE Value	Lifetime 90th% Exposure Estimates (mg/kg bw/day)
			Mean	Mean std err	90th%	90th% std err		
Oil Neutra	6691	94.9	52.68	0.97	118.4	2.45	2.1	102.2*

Creme runs #397
*Creme warning -2048, "Number of days per person should be constant for a Foods calculation" (data may still be used)

According to the estimates above, approximately 95% of the U.S. total population (ages 2 and above) was identified as potential consumers of Ceramosides™ Oil Neutra from the proposed food uses. The lifetime 90th percentile estimated exposure to Ceramosides™ Oil Neutra was 5268.3 mg/day (102.2 mg/kg bw/day). It should be noted that these estimates are considered extremely conservative, as they assume that 100% of the numerous intended use food products in the market will contain the maximum intended use levels of the SEPPIC product.

ICH guidelines state that exposure from a product to class 3 solvents should be no more than 50 mg/day. Based on the intended use and exposure estimates compiled above, the solvent specification for ethanol of <0.90% for Ceramosides™ Oil Neutra allows for a very conservative maximum exposure of 47.4 mg ethanol/day, which is within the ICH guideline.

Part 4: Self-Limiting Levels of Use

There are no known inherent self-limiting levels of use.

Part 5: Experience Based on Common Use in Food Prior to 1958

The GRAS conclusion for Ceramosides™ Oil Neutra is based on scientific procedures, and thus, experience based on common use in food prior to 1958 is not considered pivotal information. To the best of our knowledge, Ceramosides™ Oil Neutra was not commonly used in foods prior to 1958.

Part 6: Narrative

6.1 Absorption, Distribution, Metabolism, and Excretion (ADME)

As previously discussed, Ceramosides™ Oil Neutra contains TAGs, sphingolipids, galactolipids (e.g. DGDG and MGDG), phospholipids, and other minor lipid components found in wheat. These lipids are all ubiquitously consumed daily through the diet. Ingested lipids are broken down into FFAs, 2-monoacyglycerol, unesterified cholesterol and other metabolites, and are readily absorbed by enterocytes of the small intestine. Lipids are ultimately transported to the blood and peripheral tissues for utilization in the body, storage or excretion.[9]

Lipid digestion begins with enzyme activity from lingual lipase in the saliva and gastric lipase secreted from the gastric mucosa. As the dietary lipid moves through the digestive tract into the small intestine, emulsification occurs when bile salts and peristaltic mixing help to create a larger surface area on lipid droplets. This allows digestive enzymes from the pancreas to aid in further lipid breakdown.[9]

Products of lipid digestion form mixed micelles together with bile salts. These disc-shaped clusters are soluble in the aqueous environment of the small intestine because of their hydrophilic groups on the outer surface. Mixed micelles aid in absorption of longer chain fatty acid groups with the help of enterocytes at the brush border. Once lipids are absorbed by enterocytes, they migrate to the endoplasmic reticulum (ER) where biosynthesis of complex lipids take place.[9]

6.1.1 Fate of Triacylglycerol and Free Fatty Acids

Most triacylglycerol will undergo hydrolysis in the small intestine producing FFAs, mono- and diacylglycerols, and glycerol, with less than 10% remaining unhydrolyzed. After absorption, the FFAs, mono- and diacylglycerol, and glycerol are resynthesized as TAGs within the enterocytes, secreted into the lymph, packaged as chylomicrons, and transported to peripheral tissues of heart, muscle and adipose. TAGs in adipose tissue are under hormonal regulation. Hormones will initiate a phosphorylation signaling cascade resulting in the activation of hormone sensitive lipase and subsequent hydrolysis of a fatty acid from the glycerol backbone. This allows diacylglycerol lipase, followed by monoacylglycerol lipase, to act sequentially, resulting in complete hydrolysis of the TAG molecule and liberation of three FFAs and one glycerol per TAG. FFAs then move from the adipocyte to the blood stream via passive diffusion where they complex with albumin and are circulated to distant tissues for cellular uptake.

Some FFAs, in addition to their utilization as an energy substrate or resynthesis into TAGs, can contribute to the synthesis of phospholipids within local cell membranes where they serve structural, regulatory, or transport roles.[10] Glycerol that is released

from TAG is mainly used by the liver to produce glycerol 3-phosphate, which can enter glycolysis or gluconeogenesis metabolic pathways. Remnants of chylomicrons which include phospholipids, cholesterol esters, apolipoproteins and some TAG will bind to receptors in the liver where they are endocytosed and hydrolyzed, at which point they may be recycled by the body.[9]

Oxidation of FFAs for energy production takes place within the mitochondria via the β-oxidation pathway. Metabolic activation of FFAs for β-oxidation requires the addition of coenzyme A (CoA) to the carboxylic acid head of the FFA which is catalyzed by a fatty acyl-CoA ligase, resulting in the formation of an acyl-thioester CoA conjugate. Short- or medium-chain fatty acids move freely through the mitochondrial membrane and interact with their specific ligases within the mitochondrial matrix. However, FFAs with 13 or more carbons in their hydrocarbon tail require a specific transport system due to the impermeability of the inner mitochondrial membrane to long-chain fatty acids and acyl-CoAs. Long-chain fatty acid (LCFA) specific ligases are present in the outer mitochondrial membrane, where an acyl-CoA is formed. Acyl-CoA then enters the carnitine shuttle system in which carnitine acyltransferase I and carnitine acyltransferase II, respectively, replace CoA with carnitine on the outer membrane (forming an intermediate fatty acyl-carnitine) and carnitine with CoA on the inner membrane releasing the acyl-CoA within the matrix. Carnitine acyltransferase I also plays a role in the regulation of fatty acid metabolism as it is strongly inhibited by the first intermediate product in de novo fatty acid synthesis and can decrease β-oxidation of LCFA under conditions that favor synthesis.[10]

The ketogenic pathway is prominent during starvation or intentional prolonged fasting states. When dietary carbohydrates are limited or unavailable, the supply of citric acid cycle intermediates becomes limited, resulting in accumulation of acetyl-CoA derived from β-oxidation. When acetyl-CoA enters the citric acid cycle, it combines with oxaloacetate to form citrate. When levels of acetyl-CoA rise, the β-ketothiolase reaction reverses, resulting in generation of acetoacetyl-CoA from two acetyl-CoAs. The β-hydroxy-β-methylglutaryl-CoA (HMG-CoA) synthase enzyme catalyzes the formation of HMG-CoA by the addition of a third acetyl-CoA to acetoacetyl-CoA, which, within the mitochondria, is split by HMG-CoA lyase to form acetoacetate and acetyl-CoA. Acetoacetate may be reduced to form D-β-hydroxybutyrate in an NADH-dependent reaction catalyzed by β-hydroxybutyrate dehydrogenase or, in small amounts, may spontaneously degrade to yield acetone. Collectively, acetoacetate, β-hydroxybutyrate, and acetone are referred to as ketone bodies. Ketogenesis occurs primarily in the liver and the ketone bodies are then transported to peripheral tissues where they can be utilized for energy production.[10]

6.1.2 Fate of Sphingolipids

After ingestion, sphingolipids (e.g., ceramides and sphingosine) are hydrolyzed in the small and large intestine into metabolites. Sphingosine (amino alcohol + unsaturated hydrocarbon) and ceramides (sphingosine + N-acyl CoA) are rapidly taken up by intestinal cells and metabolized to FFAs.[11] A small amount of dietary sphingolipids are transported through the mucosa and appear in systemic circulation. Chylomicrons may be involved in the transport of sphingolipids as they are components of serum lipoproteins.[11]

There is no evidence that intake of sphingolipids through the diet is essential under normal conditions unless there is a defect in serine palmitoyl-transferase, the predominant enzyme in sphingolipid synthesis.[11] When there is abundant exogenous lipid intake, de novo synthesis is suppressed.[12] The regulation of sphingolipids is tightly controlled in the body and there is evidence that cells have mechanisms which sense and coordinate sphingolipid production. Enzymes and substrates particular to sphingolipid metabolism are embedded in, and not diffusible through the plasma membrane. This allows for independent regulation of enzyme activity in subcellular locations corresponding to differences in sphingolipid quantities and function. Many reactions involved in sphingolipid metabolism are reversible, which allows for rapid interconversion of different metabolic intermediates and aides in the recycling of sphingolipids and the generation of "signaling" metabolites.[12]

The end products and biosynthetic intermediates of sphingolipid metabolism have biological activity when properly regulated and, if improperly regulated due to certain disease states such as Tay-Sachs, Niemann-Pick, Farber's Disease, Fabry Disease and Gaucher Disease, may result in cellular stress and pathological effects (e.g., inhibition of sphingolipid synthesis can block growth, while overproduction can trigger toxic effects[12]). These diseases are all relatively rare in occurrence, inherited, and are not caused by consumption of dietary sphingolipids.

Studies performed in mice show that not all sphingolipids taken in through diet are hydrolyzed and absorbed. Germ-free mice show reduced hydrolysis of sphingomyelin resulting in 43% of sphingolipids excreted in feces (25–60% ceramide and 40–70% intact molecule) while non-germ-free mice were found to have only 25% excreted in feces (80–90% ceramide, 3–6% free sphingosine and 10% intact molecule).[11] Along with gastrointestinal microbiota, other factors that will impact hydrolysis and absorption include the amount of sphingomyelin absorbed, the presence of bile salts, and the levels of enzymes present.[13]

Glycosphingolipids are a type of sphingolipid derived from ceramide that contain a carbohydrate moiety attached by an O-glycosidic bond. The type of glycosphingolipid will vary depending on the number and type of carbohydrate present. Glycosphingolipids are essential components of all cell membranes in the body and are found largely in nerve tissue.[3] Exogenously consumed

glycosphingolipids are broken down through hydrolysis in the small intestine where glycolipase activity is highest, leading to the formation of FFAs and galactolipids such as MGDG and DGDG.[14 15]

6.1.3 Fate of Galactolipids

After ingestion, galactolipids such as DGDG are hydrolyzed in the small intestine where bile salts and galactolipases are responsible for the release of FFAs, digalactosylmonoacylglycerol (DGMG), and water-soluble galactose containing compounds.[15] The hydrolysis of galactolipids is similar to that of phospholipid hydrolysis, whereby galactolipids are degraded into lysocompounds which allows for their absorption and use in mucosal cells.[15] Compounds released from galactolipid breakdown will then follow similar pathways as described in the fate of FFAs, where they will serve as energy substrates, be resynthesized into TAGs, or be synthesized into phospholipids serving structural, regulatory, or transport roles.[10] According to the Human Metabolome Database, the conversion of DGDG may also be irreversibly hydrolyzed to MGDG by alpha-galactosidase.[16]

6.1.4 Fate of Phospholipids

Pancreatic enzymes facilitate phospholipid degradation. Phospholipase A2 is activated by trypsin and cleaves fatty acids from carbon two of a phospholipid, leaving a lysophospholipid. The remaining fatty acid at carbon one is removed by lysophospholipase, leaving a glyceryl phosphoryl base that can be excreted in the feces, further degraded or absorbed. Lysophospholipids are reacylated to form phospholipids by acyltranferases.[9] Phospholipids are important components of cell membranes while non membrane-bound phospholipids serve as components of lung surfactant and bile.[3]

6.1.5 Conclusion

In summary, Ceramosides™ Oil Neutra is extracted from wheat seed, and contains no less than 95% lipids including TAGs, sphingolipids, galactolipids and phospholipids. Humans have ubiquitously consumed these types of edible lipids through food intake (including from wheat seed) for millennia.[11] The metabolic pathways of these compounds have been studied and are well-described.

6.2 Toxicology Studies

No published studies investigating the potential toxicological effects of wheat lipid extracts were located during our literature searches. Likewise, no toxicological investigations of sphingolipids were located. This is likely due to the fact that both

wheat and its lipid constituents have been common components of the human diet for millennia without safety concerns, and the endogenous nature of sphingolipids, which are ubiquitously present (under homeostatic regulatory control) as components of all body cell membranes. Regardless, SEPPIC sponsored acute toxicity studies on Ceramosides™ Oil Neutra and genotoxicity and subchronic studies on a similar product, Ceramosides™ Powder Neutra. The manufacturing process of Ceramosides™ Powder Neutra begins exactly the same as Ceramosides™ Oil Neutra. However, after the initial production of wheat oil, acetone is added to the solution. Triglycerides and acetone are then decanted and the remaining polar lipids in the solution are filtered. A polar lipid paste remains that is then dried to create the final powdered product. Ceramosides™ Powder Neutra contains similar types of constituents as Ceramosides™ Oil Neutra and provides for comparable constituent exposure, despite the fact that the quantities of the similar constituents vary in the two ingredients. As shown in Table 9, Ceramosides™ Powder Neutra has a greater percentage of sphingolipids and DGDG and less triglycerides than Ceramosides™ Oil Neutra. As shown in Table 10, the fatty acid composition of the two products is approximately similar. While the ingredients are not identical and the studies are currently unpublished, the data serves to corroborate the safety of Ceramosides™ Oil Neutra. Study descriptions and results are summarized below. All studies were Good Laboratory Practice (GLP) compliant.

Table 9. Approximate Compositional Comparison of Ceramosides™ Powder Neutra and Ceramosides™ Oil Neutra

	Ceramosides™ Powder Neutra	Ceramosides™ Oil Neutra
Composition	**Content %**	**Content %**
Sphingolipids	50 %	15 %
DGDG	40 %	15 %
Phospholipids	5 %	10 %
Triglycerides	5 %	60 %

Table 10. Approximate Fatty Acid Compositional Comparison of Ceramosides™ Powder Neutra and Ceramosides™ Oil Neutra

Common Name	Fatty Acids Lipid numbers + Δ^X	Ceramosides™ Powder Neutra (g /100 g of total fatty acids)	Ceramosides™ Oil Neutra (g/100 g of total fatty acids)
Myristic	C14:0	0.02 ± 0.04	0.03 ± 0.06
Pentadecanoic	C15:0	0.08 ± 0.04	0.07 ± 0.06
Palmitic	C16:0	19.96 ± 0.22	19.17 ± 0.61
Palmitoleic	C16:1, *cis*-Δ^9	0.20 ± 0.00	0.23 ± 0.06

Fatty Acids Common Name	Lipid numbers + Δ^X	Ceramosides™ Powder Neutra (g /100 g of total fatty acids)	Ceramosides™ Oil Neutra (g/100 g of total fatty acids)
Margaric	C17:0	0.20 ± 0.00	0.13 ± 0.06
Heptadecenoic	C16:1, *cis*-Δ^{10}	0.08 ± 0.04	0.00 ± 0.00
Stearic	C18:0	0.88 ± 0.08	0.70 ± 0.00
Oleic	C18:1, *cis*-Δ^{9}	7.68 ± 0.20	11.50 ± 0.26
Linoleic	C18:2, all-*cis*-$\Delta^{9, 12}$	66.56 ± 0.38	62.70 ± 0.89
Alpha-linolenic	C18:3, all-*cis*-$\Delta^{9, 12, 15}$	3.52 ± 0.04	3.90 ± 0.10
Arachidic	C20:0	0.02 ± 0.04	0.10 ± 0.00
Gadoleic	C20:1, *cis*-Δ^{9}	0.20 ± 0.00	0.53 ± 0.06
Eicosadienoic	C20:2, all-*cis*-$\Delta^{11, 14}$	0.10 ± 0.00	0.1 ± 0.00
Behenic	C22:0	0.24 ± 0.05	0.10 ± 0.00
Erucic	C22:1, *cis*-Δ^{13}	0.00 ± 0.00	0.10 ± 0.00
Docosahexaenoic	C22:6, all-*cis*- $\Delta^{4, 7, 10, 13, 16, 19}$	0.00 ± 0.00	0.13 ± 0.00
Tricosanoic	C23:0	0.00 ± 0.00	0.03 ± 0.06
Lignoceric	C24:0	0.24 ± 0.09	0.40 ± 0.44
Nervonic	C24:1, *cis*-Δ^{15}	0.06 ± 0.05	0.10 ± 0.10

6.2.1 Acute Toxicity Study

SEPPIC sponsored an unpublished, independent investigation, in accordance with OECD test guideline (TG) 423 (adopted 21 July 1997), of the acute oral toxicities of Ceramosides™ Oil Neutra ingredient.

In the toxicity study, three female Sprague Dawley rats were observed for a period of fourteen days. Each rat was administered by gavage a single dose of 5000 mg/kg bw of Ceramosides™ Oil Neutra on day zero of the study. Animals underwent daily systemic examinations to record any behavioral or toxic effects. Their weight was recorded on days zero, two, seven and fourteen of the study. On day fourteen, the animals were euthanized by sodium pentobarbital administration. The study reported no changes upon macroscopic evaluation of organs, body weight gain was comparable to historical control, and there were no observed adverse reactions. In conclusion, the acute oral LD_{50} of Ceramosides™ Oil Neutra was considered to be higher than 5000 mg/kg bw.

6.2.2 Bacterial Reverse Mutation Test

Purpose: In order to evaluate the mutagenic potential of Ceramosides™ Powder Neutra, a bacterial reverse mutation test was conducted in accordance with OECD TG 471 (adopted 21 July 1997).

Methods: Four strains of *Salmonella typhimurium* (TA98, TA100, TA1535 and TA1537) and one strain of *Escherichia coli* (WP2 *uvrA*) were used in the presence and absence of rat liver S9 metabolic activation with appropriate positive and negative controls. The concentrations of Ceramosides™ Powder Neutra used for the initial mutation test using a plate incorporation procedure and confirmatory mutation test using a pre-incubation procedure were: 5000, 1600, 500, 150, 50, and 16 µg/plate. Three replicates were conducted for each test concentration and control (untreated, vehicle, and positive reference).

Results: Spontaneous revertant colony numbers of the vehicle control were comparable with historical control data, and positive controls induced the expected responses. No biologically relevant increases were seen in revertant colony numbers in any of the five bacterial strains upon treatment with the test item at any of the concentration levels either in the presence or absence of the S9 activation system. All results were unequivocally negative according to the study criteria for both positive and biologically relevant responses.

Conclusions: Under the experimental conditions applied, Ceramosides™ Powder Neutra failed to induce gene mutations by base pair changes or frameshifts in the genome of the strains used at concentrations up to the maximum recommended test concentration of 5000 µg/plate.

6.2.3 In vitro Mammalian Chromosomal Aberration Test

Purpose: In order to evaluate the clastogenic potential of Ceramosides™ Powder Neutra, an in vitro mammalian chromosomal aberration assay was conducted in accordance with OECD TG 473 (adopted 29 July 2016).

Methods: Ceramosides™ Powder Neutra was suspended in Dulbecco's Modified Eagle's solution, and three concentrations (1250, 2500, and 5000 µg/mL) were chosen on the basis of preliminary cytotoxic investigations. The chromosomal aberration assays were conducted in two independent experiments (each in duplicate) using V79 (Chinese hamster lung) cells. The cells were exposed to the negative control or each test item concentration with and without metabolic activation using rat liver S9. Groups of cells were also exposed to the respective positive controls for use with or without S9-mix. Ethyl methanesulfonate was used as positive control without S9-mix and cyclophosphamide was used as the positive control with S9-mix. Exposure and sampling times were as follows:

- Experiment A: 3h treatment with and without S9-mix (1250, 2500, and 5000 µg/mL)/20h sampling time.
- Experiment B: 20h treatment without S9-mix (1250, 2500, and 5000 µg/mL)/20 and 28h sampling times.

- Experiment B: 3h treatment with S9-mix (1250, 2500, and 5000 µg/mL)/28h sampling time.

Following treatment and sampling, cells were exposed to selection agent, colchicine (0.2 µg/mL), 2.5 hours prior to harvesting and fixing for slide preparation. Chromosome aberration frequencies were then scored blind for at least 300 well-spread metaphase cells.

Results: In both A and B experiments, no statistically significant differences compared to concurrent and historical negative (solvent) controls in numbers of chromatid or chromosome aberrations or in the rate of polyploid and endoreduplicated metaphases were observed after treatment with the different concentrations of Ceramosides™ Powder Neutra with or without metabolic activation. No dose-response relationships were noted.

Conclusions: Ceramosides™ Powder Neutra is not clastogenic in this test system.

6.2.4 In vivo Mammalian Micronucleus Test

Purpose: In order to evaluate the genotoxic potential of Ceramosides™ Powder Neutra, an in vivo mammalian micronucleus assay was conducted in accordance with OECD TG 474 (adopted 29 July 2016) under the permission of the Institutional Animal Care and Use Committee (IACUC) of Toxi-Coop Zrt.

Methods: Two doses of Ceramosides™ Powder Neutra were administered by gavage at 24-hour intervals to male Crl:NMRI BR mice at test concentrations of 0 (vehicle-control), 500, 1000, or 2000 mg/kg bw. The high dose is the limit dose for mammalian erythrocyte micronucleus tests. The negative control/vehicle was 1% aqueous methylcellulose. The positive control, cyclophosphamide, was administered by intraperitoneal injection at a concentration of 60 mg/kg bw. Each group consisted of five animals, and all treatments were administered at a uniform volume of 10 mL/kg bw. The micronucleus test was conducted at the doses described above in males only based on the results of a non-GLP, preliminary toxicity test that was conducted using a single gavage dose of Ceramosides™ Powder Neutra at a concentration of 2000 mg/kg bw in two animals/sex/group in order to determine the high-dose and assess sex differences. No mortality, signs of toxicity, or sex specific effects were observed in the preliminary test.

All animals were observed immediately following dosing and at regular intervals until sacrifice for mortality, signs of toxicity, or adverse reactions to treatment. Bone marrow smears were prepared in duplicate on standard microscope slides from samples obtained from the femurs of each animal from each dose group immediately following sacrifice 24 hours after the second treatment (after the single treatment in the positive controls). Four thousand polychromatic erythrocytes (PCE) per animal were scored for frequency of micronuclei with one slide from each animal being

scored blind. The proportion of PCE to mature erythrocytes per animal was determined by the number of mature cells encountered while counting at least 500 PCE.

Results: No mortality, clinical signs of toxicity, or adverse reactions to treatment were observed in any animals during the study. No significant differences were observed in frequency of micronucleated PCE or proportion of PCE to mature erythrocytes between the three dose groups compared to the negative control, and all results were within the laboratory's historical control range. A slight non-significant decrease in PCE in the high-dose group compared to concurrent negative controls indicated exposure of the test item to bone marrow occurred.

Conclusions: Ceramosides™ Powder Neutra, at concentrations up to the limit dose of 2000 mg/kg bw, was negative for producing chromosomal damage in the bone marrow of mice under the experimental conditions supplied.

6.2.5 Twenty-eight-day, Repeated-Dose Oral Toxicity Study

Purpose: An unpublished 28-day study was conducted in accordance with OECD TG 407 (adopted 03 October 2008) as a preliminary evaluation of the potential health hazards, including identification of toxic effects and target organs, of repeated oral exposure to Ceramosides™ Powder Neutra. The study was conducted under the permission of the IACUC of Toxi-Coop Zrt and in compliance with the National Research Council Guide for Care and Use of Laboratory Animals[17] and the principles of the Hungarian Act 2011 CLVIII (modification of Hungarian Act 1998 XXVIII) regulating animal protection.

Methods: Ten SPF Hsd.Han Wistar rats/sex/group were administered Ceramosides™ Powder Neutra (formulated in a sunflower oil vehicle) at concentrations to provide for uniform administration by gavage of a dose volume of 10 mL/kg bw. Four groups were administered doses of 0 (vehicle-control), 500, 1000, and 2000 mg/kg bw/day for 28 days.

All tests and examinations were conducted according to study protocols and in compliance with above stated guideline.

Results: Sporadic increases in body weight were noted in the high-dose male group and in all female test groups. As the findings were transient in both sexes and additionally not dose related in the female group, the finding was not considered test item related.

A statistically significant increase in total protein was noted in the male low- and mid-dose groups. A statistically significant decrease in calcium was seen in the male mid- and high-dose groups, and a statistically significant decrease in phosphorus was noted in the male mid-dose group compared to controls. Additionally, in the female groups, increased creatinine was observed in the low-dose group; the mid-

dose group had an increase in alanine aminotransferase, an increase in creatinine, a decrease in sodium, and an increase in albumin to globulin ratio; and the high-dose had an increase in cholesterol and decrease in calcium. All changes were statistically significant. These changes were considered normal physiologic variations and corresponded well with historical control (within or marginal to the historical reference range of the lab). Additionally, none of the changes were seen in both sexes and many changes were noted only in low- or mid-dose groups. Therefore, the changes are not considered to be test item related.

Organ weights were normal for the low- and high-dose groups compared to the control. Brain weight was statistically significantly low for both absolute and relative to body weight and body weight was elevated relative to brain weight in the male mid-dose group. As the changes were not dose dependent, they were not considered toxicologically relevant.

Pyelectasis was reported in low incidence in all male test groups and in one female in the mid-dose. This is a common finding in this strain of rats and is not considered toxicologically relevant. Hernia diaphragmatica was seen in the control, low- and mid-dose males at low incidence. This structural change is common in the strain of rat studied and, due to its low- and non-dose-related incidence, is not considered test item related. Hydrometra was observed in similar incidence in all female groups and, as it is a common neurohormonal response to the estrous cycle in female rats, is not considered toxicologically relevant. A thymus hemorrhage was observed in one female of the high-dose test group. This was considered a result of the exsanguination process and not test item related. A single male in the high-dose group had both an adhesion on the liver and a cyst on an adrenal gland. As it was in the same male, it was considered an individual change and not test item related. No inflammatory or pathologic lesions were noted in any of the examined organs.

Histopathologic examination was performed on the control and high-dose groups, as well as on any abnormal macroscopic organ observations. Examination revealed centrilobular vacuolation in control and high-dose males and females. This finding suggests possible hepatic lipidosis. Due to the fact it was seen in both control and test groups, it was not considered toxicologically relevant. Acute emphysema was noted in one male at the high-dose group and thymic hemorrhage was noted in one female in the high-dose group. These findings are common with hypoxia during exsanguination and are not considered test item related. Interstitial fibrosis of the liver (focal, subcapsular) was noted in one control male and was attributed to irritation of Glisson's capsule due to hernia diaphragmatica. It is not considered test item related as it was in a control animal.

In summary, none of the following were affected by test article administration: mortality, body weight or body weight gain changes, changes in mean daily food consumption and feed efficiency, pathologic changes in the evaluated hematological

or blood chemistry parameters, specific macroscopic changes in the gross pathology findings, ophthalmologic changes, changes in absolute or relative organ weights, or histopathological lesions.

Conclusions: Oral administration of Ceramosides™ Powder Neutra at doses up to 2000 mg/kg bw/day for 28 days did not cause signs of toxicity in male or female SPF Hsd.Han Wistar rats. Based on these results, the no observed adverse effect level (NOAEL) was determined to be 2000 mg/kg bw/day; the highest dose tested.

6.2.6 Summary of Toxicity Study Results

As demonstrated in the study summaries above, Ceramosides™ Powder Neutra showed no mutagenic effect in the Ames or micronucleus assays. A subchronic toxicity study on Ceramosides™ Powder Neutra showed no effects up to 2000 mg/kg bw, the highest dose tested. While the information is unpublished and the test article is not identical to Ceramosides™ Oil Neutra, it helps support the safety narrative that Ceramosides™ Oil Neutra is not toxic.

6.3 Human Studies

A placebo-controlled, randomized, and double blind clinical study (n=60) comparing the effect of oral intake of Ceramosides™ Oil Neutra (70 mg/day x 60 days) to placebo on skin hydration and age-related symptoms (skin elasticity, smoothness, trans epidermal water loss, roughness and wrinkling) was published in 2017.[18] The authors reported no adverse effects and the test article was well tolerated throughout the 60-day studies.

6.4 Allergenicity

Ceramosides™ Oil Neutra has undergone extensive testing for the wheat proteins, gluten and gliadin. Levels are confirmed to be < 3 ppm which is below the maximum limit for status of "gluten-free" under FDA standards. Ceramosides™ Oil Neutra raw material does not contain and is not exposed to any additional allergens through the manufacturing process. In addition, there is no allergenic potential of wheat lipids or sphingolipids mentioned in the public domain.

6.5 History of Consumption

Wheat consumption began in the Fertile Crescent of the Middle East approximately 10,000 years ago when humans transitioned from a hunting and gathering lifestyle to farming with the domestication of wheat. Today, approximately 430 million tons of domesticated wheat (known as bread wheat or common wheat) is produced

annually and estimated to provide about 1/5 of the calories consumed by humans worldwide.[20]

According to survey data extracted from NHANES 2014 WWEIA, the average lifetime consumption of fat in the United States was approximately 80 g/day, while the 90th percentile lifetime consumption was approximately 116 g/day.[21] As discussed in Part 3, lifetime 90th percentile exposure to Ceramosides™ Oil Neutra, which is > 95% lipids, is estimated at 5.3 g/day. As this product could potentially be additive with regard to fat intake in the diet of consumers, Ceramosides™ Oil Neutra would increase the amount of fat consumed in the United States at the 90th percentile by up to approximately 4.5% (5.3 g/day of fat from Ceramosides™ Oil Neutra/116 g/day of fat from average American consumption). However, it is also possible that the ingredient will be substitutive for other oil ingredients in the intended use food categories.

Sphingolipids are constituents of many foods in relatively small quantities. As they are present in all cellular membranes, sphingolipids are found both in animal and vegetable foods. Sphingolipid concentrations can vary widely depending on the food type, with high fat dairy products like cream and cheese containing about 1692 μmol/kg and 1326 μmol/kg, respectively; eggs containing approximately 2250 μmol/kg; soybeans containing approximately 2410 μmol/kg; and wheat containing approximately 576 μmol/kg. Due to its high consumption per capita, wheat generally constitutes approximately 25% of the total annual sphingolipid consumption.[11] Average sphingolipid consumption varies widely as a function of dietary habits. In the USA, the average sphingolipid consumption per capita is estimated at 0.3 to 0.4 g/day.[11]

Glycolipids, such as DGDG, are major lipids in photosynthetic tissue of vegetable food but are also found in non-photosynthetic tissue such as potato tubers, apples, and seeds. Cereals such as barley, corn and wheat flour are rich in DGDG. Wheat flour has been reported to contain 158–230 mg DGDG per 100 g dry weight. The differences in values stem from the method of quantification and from natural variation in the raw material as plant glycolipid content can vary tremendously depending on the cultivar, growth conditions, stage of development and the day of harvest.[22] The Wheat Foods Council in 2004 estimated the daily intake of wheat flour to be about 165.3 g/day, which, based on the amount of DGDG in wheat flour described above, would approximate to a daily intake of DGDG from wheat flour to 260–380 mg/day for the average American.[23] In a 2012 Scientific Opinion on the substantiation of a health claim related to oral intake of Wheat Polar Lipid Extract (submitted by Extraction Purification Innovation France) and protection of the skin against dehydration, the European Food Safety Authority (EFSA) discussed the background consumption levels of ceramides and DGDG. EFSA's opinion was that the dose of 30 mg/day of the Wheat Polar Lipid Extract (providing 1.8 mg/day of

ceramides and 15 mg/day of DGDG), based on an unpublished clinical trial, would represent only a small fraction (about 10%) of the quantity that would be consumed in the diet by subjects eating a typical amount of wheat-derived foods.[19] Though 30 mg/day is below the anticipated exposure estimates outlined in Part 4 of this document, it serves as corroborative evidence of the safety of Ceramosides™ Oil Neutra.

6.6 Past Sales and Reported Adverse Events

No FDA letters regarding concern for safety to companies that market products containing ceramosides, wheat cerasomes, wheat ceramosides oil, wheat seed extracts, sphingolipids, phosphatidylethanolamine, phosphatidylcholine, phosphatidylinositol, or lysophosphatidylcholine were located.

Additionally, according the manufacturer E.P.I France, no adverse events have been reported with respect to the ingredient following sale of 7525 kg of Ceramosides™ Oil Neutra from 1998–2019 in various countries.

6.7 Similar Products in the Marketplace

A general internet search as well as searches of the National Institutes of Health (NIH) Dietary Supplements Label Database and large distributors of dietary supplements resulted in a number of findings of wheat lipid extract(s) products, illustrating this type of ingredient is available in the United States. Examples of wheat lipid extracts are listed in Table 11:

Table 11. U.S. Products Containing Wheat Lipid Extracts

Company	Product Name	Serving Size(s)
Life Extension	Skin Restoring Ceramides https://www.lifeextension.com/Vitamins-Supplements/item02096/Skin-Restoring-Ceramides	350 mg daily Ceratiq® wheat (*Triticum vulgare*) oil extract (providing glycolipids, phytoceramides and glycosylceramides)
Sports Research	Phytoceramides https://sportsresearch.com/products/phytoceramides?variant=36601562726 80	350 mg daily Phytoceramides from non-GMO wheat (*T. vulgare*)
Healthy Choice Naturals	Phytoceramide Complex http://shop.healthychoicenaturals.com/Phytoceramides-Skin-Rejuvenating-Complex-p/phyto.htm	350 mg daily Phytoceramides daily complex consisting of wheat germ oil and phytoceramides from (wheat extract)
Douglas Laboratories	Skin Nourish https://www.douglaslabs.com/skin-nourish.html	30 mg daily Ceramosides™ Ceramide wheat seed extract (*T. vulgare*), (standardized to 50% glycosylceramides, 40% DGDG)
Reserveage	Collagen Hydra Booster with phytoceramides	30 mg daily

	https://reserveage.tlcchealth.com/product/collagen-hydra-booster-ceramides/	Ceramosides™ Ceramide wheat extract (*T. vulgare*) (seed) standardized to 50% glycosylceramides (7.5 mg), 40% DGDG (6 mg)
ResVitale Collagen Hydraplump with Ceramides	Ceramosides™ Ceramide Wheat Extract http://www.resvitale.com/product/collagen-hydraplump-with-ceramides/	15 mg Ceramosides™ Ceramide Wheat Extract (*T. vulgare*) (seed) standardized to 50.0% glycosylceramides, 40.0% DGDG

6.8 Current Regulatory Status

A thorough search for the current regulatory status of Ceramosides™ Oil Neutra, wheat seed extract, phospholipids, sphingolipids, ceramides, cerebrosides, and DGDG relevant to use in food in the United States was conducted. Searched databases included: List of NDI Notifications (NDIN[24]), FDA GRN (GRAS) inventory, 21 CFR, and a general internet search. A summary of the pertinent search results is shown below:

- An NDI notification to FDA (NDI 856)[25] was provided by SEPPIC and found in the FDA list of NDINs, for Ceramosides™ Oil Neutra. NDI 856 received a "no questions" letter from the Division of Dietary Supplement Programs, CFSAN, on February 19, 2015 for the use of Oil Neutra at a serving level of 70 mg/day for healthy adults.

6.9 Basis for the GRAS Conclusion

The scientific procedures establishing the safety of Ceramosides™ Oil Neutra comprise the technical element of the GRAS standard. The common knowledge element is comprised of the general availability and general acceptance, throughout the scientific community of qualified experts, of the technical element. Together, the technical element and the common knowledge element form the basis for SEPPIC's conclusion of GRAS status of Ceramosides™ Oil Neutra for its intended use.

6.9.1 Data and Information that Establish Safety

The scientific data, information, and methods forming the basis of this conclusion are:

- The establishment of identity, demonstrating composition of the ingredient as commonly consumed edible lipids;

- The method of manufacture and specifications, demonstrating safe production and high-quality control standards for Ceramosides™ Oil Neutra;
- ADME data demonstrating the well-studied pathways by which the body metabolizes the edible lipids that comprise Ceramosides™ Oil Neutra;
- The long history of daily high consumption of wheat, and hence wheat lipids, in the human diet, and the ubiquitous presence of sphingolipids, glycolipids (e.g. DGDG) and TAGs from other standard foods in the diet.

The Ceramosides™ Oil Neutra product contains no less than 95% of lipids from wheat, which have been consumed ubiquitously for millennia. The exposure estimates based on the ingredient's intended uses suggest a lifetime 90th percentile exposure of 5268 mg/day of Ceramosides™ Oil Neutra. The 90th percentile lifetime exposure estimate is extremely conservative in that it assumes the ingredients are present in 100% of the food items in each of the intended use food categories, and they are not expected to result in any significant material increase in exposure to total fat beyond what is ingested through typical dietary exposure, as described in Part 6.5. The individual lipids found in the ingredient have well-described ADME pathways in the human body and are expected to be readily metabolized. As such, the totality of evidence supporting safety of the ingredient as described in this subpart supports a conclusion that the intended uses of Ceramosides™ Oil Neutra are reasonably certain to be safe.

6.9.2 Data and Information that is Corroborative of Safety

The safety of Ceramosides™ Oil Neutra is corroborated by unpublished genotoxicity studies and a twenty-eight-day repeated-dose oral toxicity study in rats on a powdered wheat lipid extract (Ceramosides™ Powder Neutra) with a NOAEL of 2000 mg/kg bw/day, the highest dose tested, along with the lack of serious adverse events reported in a clinical trial using Ceramosides™ Oil Neutra at daily dosages up to 70 mg/day and durations up to 60 days, and the history of human consumption of approximately 7525 kg (more than approximately 107 million 70 mg servings) of Ceramosides™ Oil Neutra over a 20-year period with no serious adverse event reported. Additionally, a NDI notification to the FDA with no questions at the suggested dosage of 70 mg/day further corroborates the product's safety. While the exposure in the clinical trial and the NDI notice were at much lower exposures compared to those estimated for the intended uses in this GRAS conclusion, they add to the general corroboration of the safety of the ingredient at levels that may be typically found in a serving of food containing Ceramosides™ Oil Neutra.

6.9.3 General Recognition

The scientific data, information, and methods herein reported, that provide the basis of this GRAS conclusion by scientific procedures are published and available in the public domain aside from the acute, genotoxicity, and subchronic toxicity studies in Part 6.2. Part 7 of this GRAS notice contains the bibliography for the published studies. This publicly available data and information fulfills the requirement for general availability of the scientific data, information, and methods relied on to establish the technical element of the GRAS standard. Additionally, the lack of Letters to the Editor or other dissenting opinions further provide reasonable certainty that consumption of Ceramosides™ Oil Neutra for its intended use is not harmful. The general availability and acceptance of this scientific data, information, and methods satisfies the common knowledge element of this GRAS conclusion.

6.10 Data and Information that are Inconsistent with the GRAS Conclusion

We have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with our conclusion of GRAS status.

6.11 Information that is Exempt from Disclosure under FOIA

There are no data or information in this report that are considered trade secret or commercial or financial information that is privileged or confidential.

Part 7: Supporting Data and Information

Initial literature searches for the safety assessment described in Part 6 of this GRAS notice were conducted through October 30, 2019.

7.1 Data and Information that are *not* Generally Available

Information described in this GRAS notice that is not generally available includes the unpublished studies described in sections 6.2. These studies are considered only corroborative as stated in 6.10.2. Pivotal information is published, as reviewed in 6.10.1.

7.2 References that *are* Generally Available

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From:	John Endres
To:	Morissette, Rachel
Cc:	Kayla Preece; Amy Clewell; Jared Brodin
Subject:	Re: GRN 906 and 907: AIBMR Response and Follow-up Question
Date:	Tuesday, May 19, 2020 3:48:51 PM
Attachments:	image001.png sugawara.pdf Polocki 2016.pdf

Dear Dr. Morissette,

Thanks very much for all that you do with such limited resources. I feel like there must be some misunderstanding and I am very sorry if we did not make it clear that we are suggesting that the client severely restrict the exposure as follows:

1. Oil Nutra: 70 mg MAX EDI (10.5 mg sphingolipids (SL)., 10.5 mg DGDG)
2. Powder Nutra: 30 mg MAX EDI (15 mg spingolipids, 12 mg DGDG)

I am attaching (2) two papers that highlight the wide range of commonly consumed foods that humans eat that contain SL and DGDG.
For example (1) one cup of skimmed milk contains 15 mg of SL. Buttermilk contains even more and it is found in yogurt, cheese, whole milk, etc.

DGDG is also found fairly ubiquitously in the vegetable kingdom in grains and many fruits and vegetable in very appreciable amounts. For example 1/8 c of pumpkin purée (think pumpkin pie and muffins) has 12 mg DGDG. (see attached paper).

It seems that the 28-day study may be pivotal if published because the following statement seems not to be the case at this severely restricted exposure (per above); "A 28-day study cannot replace the need for a 90-day study on such an ingredient that has not been consumed at the proposed level."

We were thinking a 1000-fold uncertainty factor using the NOAEL from the 28-day study of 2000 mg/kg bw/day to be ultra conservative. (2000 mg/kg bw/day) / 1000 = 2 mg/kg bw/day in humans or 140 mg/day in a 70 kg human as the ADI (when published). Since the EDI would be 70 mg/day this would be an additional significant margin of safety.

As you probably know, we have been meeting with and submitting GRAS Notifications to OFAS for well over a decade with 100% success in getting the "FDA has no questions" letter. This is why I believe there has been some significant misunderstanding. Again, we apologize if we caused unnecessary confusion.

We very much appreciate your response and thank you for your valuable time (please see further comments below).

Best Regards,

John R. Endres, ND
Chief Scientific Officer

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On Tue, May 19, 2020 at 6:52 AM Morissette, Rachel <Rachel.Morissette@fda.hhs.gov> wrote:

> Dear Kayla,
>
> I spoke with our toxicologists about your proposal below and they provided the following:
>
> A 28-day study cannot replace a 90-day study for an ingredient that has not been used before at the proposed level. As discussed below, there are various reasons why a 90-day study is required, at a minimum:
>
> 1. Although the ingredient is derived from wheat, if you consider per capita wheat consumption, along with the fact that this ingredient is a minor fraction of the whole plant grain (1.5-2.5%), the normal exposure to this ingredient through daily consumption of wheat is really low (mg/person/day). Per above, this extends far beyond wheat in the daily diet with a very long (thousands of years) history of human exposure.
> 2. Because toxicity is a function of dose (exposure), something that is normally innocuous at a lower level of exposure may turn out to be not so innocuous when a whole lot of it is consumed. I think there was a misunderstanding as the suggested new exposure would be 70 mg/d for the oil and 30 mg/d for the powder, which doesn't seem like much at all compared to the typical daily diet.
> 3. A 28-day study cannot replace the need for a 90-day study on such an ingredient that has not been consumed at the proposed level. We understand this, but since there is such an extensive history of human exposure for thousands of years and a presumption of safety, with a 1000-fold uncertainty factory and such low EDis, it would seem like the 28-day study could now be considered pivotal for the ADI after publication in a peer-reviewed journal specializing in toxicology.
> 4. Based on the findings of the 28-day study, some of the effects that have been discounted as toxicologically not important may turn out to be toxicologically relevant. We will not know that without the longer study. Since there is such a long history of human exposure to a fairly significant amount of these substances and because they are widespread in the human diet, we don't anticipate any additional findings in a longer study. Quite similarly to GRN 773 that we submitted for a never before consumed algae based upon a 28-day study (NOAEL = 4000 mg/kg bw/day) allowing 2.8 g/day using a 100-fold

uncertainty factor. Received no objection to replace up to 100% of the protein in a typical human diet (i.e. 100 g) which is 250 g of the algae.

5. Because of the distribution of sphingolipids in the body, and because of the reports of sphingolipid-induced circulating factors associated with obesity (*e.g.*, saturated fatty acids, inflammatory cytokines), one would expect that the histopathological investigation in a 90-day study would, in addition to other organs, pay special attention to the brain and also determine the inflammatory cytokine status in the blood. If this were a problem at levels currently in the diet we would all be in trouble. Perhaps you were calculating based upon the original proposed exposure rather than the now severely restricted exposure?
6. Under such conditions, applying a higher safety factor is not logical because we do not know how much the alternative safety factor should be. Perhaps this could be reconsidered per the above toxicological perspectives and risk reduction.

I hope this information if helpful.

Best regards,

Rachel

Rachel Morissette, Ph.D.
Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety
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rachel.morissette@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Kayla Preece <kayla@aibmr.com>
Sent: Monday, May 18, 2020 3:52 PM
To: Morissette, Rachel <Rachel.Morissette@fda.hhs.gov>
Cc: Amy Clewell <amy@aibmr.com>; John Endres <john@aibmr.com>
Subject: GRN 906 and 907: AIBMR Response and Follow-up Question

Dear Dr. Morissette,

Thank you very much for your email and the opinion that lowering the exposure will not be useful at this point. We are thinking that the conference call on the 27th will likely not be necessary now, but we do have one last question for you that will help us make our final decision. As the 28-day repeated dose study in rats has already been performed (but is unpublished at the moment), we would appreciate your opinion about one additional strategy. What if Seppic were to publish the 28-day study, and then, as discussed by phone, use a higher uncertainty factor (higher than 100) to determine an ADI? This would of course be in addition to lowering the exposure such that the EDI would be less than the ADI.

We truly appreciate your time and consideration in this matter, and look forward to hearing your thoughts.

--

Best regards,
Kayla

Kayla Preece, ND

Scientific and Regulatory Consultant

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From:	Kayla Preece
To:	Morissette, Rachel
Cc:	John Endres; Amy Clewell; Jared Brodin
Subject:	AIBMR-GRNs 906 and 907- FDA Responses and Requested Documents
Date:	Friday, June 12, 2020 3:11:55 PM
Attachments:	GRN 906 and 907 Response to FDA2.pdf (Q2)Statement methods and correlated versions NF EN ISO 3960_662_21528 1_V1_MAJ25052020.pdf (Q4)GRN907CoA-411191223 V9_MAJ27052019_SSA0055194.pdf (Q5)GRN906-Statement Heavy metals quantification with validated method CERAMOSIDES POWDER NEUTRA_V1_MAJ25052020.pdf (Q5)GRN906HeavyMetalAnalysis-21170530 CHA métaux lourds.pdf (Q5)GRN906HeavyMetalAnalysis-21180222 CHA métaux lourds.pdf (Q5)GRN906HeavyMetalAnalysis-21190328 pest_ML_Myco_HAP_EN.pdf (Q5)GRN907-Statement Heavy metals quantification with validated method CERAMOSIDES OIL NEUTRA_V1_MAJ25052020.pdf (Q5)GRN907HeavyMetalAnalysis-411151210 EUR Pest Myco ML.pdf (Q5)GRN907HeavyMetalAnalysis-411160523 CHA Pest Myco ML HAP_ presence HAP.pdf (Q5)GRN907HeavyMetalAnalysis-411171219 CHA (1).pdf (Q6)GRN906ResidualSolventAnalysis-21180702 CHA lexva.pdf (Q6)GRN906ResidualSolventAnalysis-21180709 CHA lexva.pdf (Q6)GRN906ResidualSolventAnalysis-21190307 lexva.pdf (Q6)GRN906ResidualSolventSpecification Internal Method V4_MAJ20052020.pdf (Q6)GRN907ResidualSolventAnalysis-411171219 CHA Lexva.pdf (Q6)GRN907ResidualSolventAnalysis-411190718 lexva.pdf (Q6)GRN907ResidualSolventSpecification Internal Method V6_MAJ20052020.pdf (Q6)GRN907ResidualSolventAnalysis-411191223 lexva.pdf

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Hello Dr. Morissette-

Please find the attached pdf with the responses to the FDA's questions along with requested documents for GRNs 906 and 907. Please let me know if you have any questions. Again, thank you for working with us through this process.

--

Best regards,
Kayla

Kayla Preece, ND

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Dr. Rachel Morissette
Regulatory Review Scientist
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
Division of Food Ingredients

June 11, 2020

Re: Regarding Responses to GRNs 906 and 907 questions

Dear Dr. Rachel Morissette,

Please find our responses to FDA questions regarding GRN 906 (Wheat polar lipids, Ceramosides™ Powder Neutra) and 907 (Wheat seed oil, Ceramosides™ Oil Neutra) in red.

As an introduction, we would like to explain that after discussion with FDA, Seppic has decided to modify the intended uses for the ingredient subjects of both GRNs 906 and 907. Each GRN will now only contain one intended use food category. The intended use for Ceramosides™ Powder Neutra in GRN 906 will now be functional beverages at a maximum concentration of 0.1 mg/g (see our response to question 7 below in for a more detailed description of NHANES food codes utilized to represent this category during exposure estimates). The intended use for Ceramosides™ Oil Neutra in GRN 907 will now be in bars at a maximum concentration of 2.0 mg/g. All other intended use food categories will be removed.

New exposure estimate assessments were performed using Creme Global software with regard to the new conditions of intended use:

- For GRN 906, the use in functional beverages is expected to lead to consumption by approximately 8.9% of the total population, a mean exposure of approximately 20.2 mg/day (0.39 mg/kg bw/day), and a 90th percentile lifetime exposure of approximately 30.7 mg/day (0.68 mg/kg bw/day).

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- For GRN 907, the use in bars is expected to lead to consumption by approximately 11.8% of the total population, a mean exposure of approximately 53 mg/day (0.85 mg/kg bw/day) and a 90th percentile lifetime exposure of approximately 71 mg/day (1.4 mg/kg bw/day).

Note that these estimated daily intake (EDI) estimates are equivalent to the levels described for use in dietary supplements in New Dietary Ingredient (NDI) notifications RPT774[1] (Ceramosides™ Powder Neutra), and NDI RPT856[2] (Ceramosides™ Oil Neutra), both of which were acknowledged without objection by FDA. These proposed levels also correlate with the levels used in the human clinical study on wheat seed polar lipids and wheat seed oil.[3]

Chemistry:

1. **GRN 000907:** On page 13 (Figure 3) of the notice, SEPPIC includes in a flow chart an "oil purification" step. According to the description of the manufacturing method, the filtrate is separated (solid/liquid separation) and concentrated by evaporation to yield the final wheat seed oil. We note that the manufacturing description does not include a purification step performed after the solid/liquid separation step. Please describe what is involved in the "oil purification" step.

Find the new description of the oil purification step below:

Wheat seed oil purification:

- Wheat seed oil is purified by mechanical stirring to allow elimination of residual proteins.
- Residual solvent is evaporated under vacuum to obtain CERAMOSIDES™ OIL NEUTRA.
- CERAMOSIDES™ OIL NEUTRA is sieved at 355 µm before magnetic gauss separation.

2. **GRNs 000906 and 000907**: On pages 14-15 (Table 3) of the notices, SEPPIC provides specifications for either wheat seed polar lipids or wheat seed oil, and specifies a method used to test for each parameter. We note that SEPPIC refers to several NF EN ISO standards for which corresponding ISO standards have been withdrawn and replaced by updated versions. Please explain why SEPPIC refers to withdrawn ISO standards and/or correct the following references: NF EN ISO 660-09/2009, NF EN ISO 3960-06/2010, NF EN ISO 662-02/2001, and NF ISO 21528.1-12/2014. In addition, please provide a statement that all methods used to test for each parameter listed in Table 3 are validated for that purpose.

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Furthermore, please confirm that the sample size for specifications listed as "absent/g" is 1 g and that the term "Enterobacteria" refers to the *Enterobacteriaceae* family.

The GLP-certified laboratory performing the analysis for Seppic uses the current versions of the appropriate methods for the parameters tested. They were not properly updated in the specifications and certificates of analyses. Please find the statements assuring analysis is performed using up to date methods. Seppic assures that all methods used to test each parameter in Table 3 are validated for that purpose. Finally, we confirm that "Enterobacteria" is Enterobacteriacea family and the specification "absent/g" is equivalent to "absent/ 1g".

3. **GRN 000906**: On pages 15-16 (Table 4) of the notice, SEPPIC provides batch analysis results for wheat seed polar lipids and states that the total sphingolipid content was calculated based on the total nitrogen content using an internal method. We note that two batches with the same percentage of total nitrogen linked to polar lipids (0.8%) have different total sphingolipid content (66.4% and 56.8%). Please explain how SEPPIC calculated the total sphingolipid content.

Method 06520 is an indirect method to calculate total sphingolipid content (S) based on

- total nitrogen content: N2, and
- phospholipid content: P (determined by HPLC --> 5 phospholipids with specific molecular weight W)

$S = (N2-N1) \times M \times 14$
with
$N1 = \Sigma (P / W \times 14)$
$M = 737.43$ g/mol mean molecular weight of total sphingolipids

As the phospholipid content is also part of the calculation, total nitrogen content is not directly linked to the total sphingolipid content and 2 different batches with the same content of total nitrogen could have different total sphingolipid contents.

4. **GRN 000907**: On pages 15-16 (Table 4) of the notice, SEPPIC provides results of two batch analyses for wheat seed oil. Please note that we typically request results from three non-consecutive batch analyses. Please provide analytical results for a third batch or explain why you are not able to provide these data.

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Since the submission of the GRAS dossier, another batch (411191223) has been produced of the wheat seed oil. Please find it attached. This batch is the last certificate of analysis that does not have residual solvent analysis included on the certificate. All batches in the future will include residual solvent analysis.

5. **GRN 000906:** On page 17 (Table 5) of the notice, SEPPIC provides heavy metal specifications for wheat seed polar lipids and specifies an analytical method used to test for heavy metals. Please provide a statement that the specified analytical method has been validated for that particular purpose. SEPPIC also states that heavy metal analyses are performed once a year. Please provide the results of three non-consecutive batch analyses to demonstrate that the ingredient meets the specifications listed in Table 5. We would also suggest that SEPPIC include specifications for heavy metals in wheat seed polar lipids and provide revised Tables 3 and 4 to reflect the specifications for heavy metals and the results of the batch analyses.

Please find the attached statement verifying that the specified analytical methods have been validated for the purpose of heavy metal analysis. Additionally, 3 batches analyzing heavy metal results of the wheat seed polar lipids are attached. Please find updated Table 3 which includes the heavy metal specification. The 3 shared heavy metal batch analyses are from batches that do not align with the batch numbers in Table 4. Therefore, their results were not added to Table 4. However, if deemed critical, we can request new certificate of analysis information to align with the heavy metal batches and update Table 4.

Table 3. Ceramosides™ Powder Neutra Specifications

Test Items	Specification	Method
Marker Compounds		
Total sphingolipids including glycosphingolipids	≥ 50%	IM 06520-V3 (indirect[1])
DGDG	≥ 40%	IM 06522-V4 (RP-HPLC, ELSD)
Total Nitrogen linked with polar lipids	≥ 0.6%	IM adapted from Dumas (combustion) NF EN ISO 16634-1-12/2008
Polar Lipids Identification[2]	Identical to assay	IM 06223-V3 (TLC)

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Physical Characteristics		
Aspect	Thin powder	Visual and Olfactive
Color	Beige to light yellow	
Odor	Cereal characteristic	
Chemical Data		
Acid Value	<15 mg KOH/g	NF EN ISO 660-09/2009
Peroxide Value	<10 mEq/kg	NF EN ISO 3960-06/2010
Humidity	< 5%	NF EN ISO 662-02/2001
Dry Extract	> 95%	NF EN ISO 662-02/2001
Microbiological Tests		
Total aerobic plate count	≤ 100 cfu/g	NF EN ISO 4833-1-10/2013
Total Yeast & Mold	≤ 100 cfu/g	NF V08-036-05/2003
Enterobacteria	Absent/g	NF ISO 21528.1-12/2014
Staphylococci coagulase + (37°C) including *Staphylococcus aureus*	Absent/g	NF EN ISO 6888.3-06/2003
Escherichia coli	Absent/g	Internal MA 104.4 adapted from ISO16649.3
Salmonella	Absent/10 g	BRD 07/11-12/05
Listeria monocytogenes[2]	Absent/25 g	ALOA-AES 10/3-09/00
Heavy Metal Tests		
Arsenic[2]	≤ 0.1 ppm	IM adapted from NF EN 15763 (ICP-MS)
Cadmium[2]	≤ 0.1 ppm	
Lead[2]	≤ 0.2 ppm	
Mercury[2]	≤ 0.1 ppm	
Solvent Analysis		
Acetone	< 30 ppm	Internal Method ref 06961_V2
Ethanol	< 5000 ppm	
Allergens		
Residual gluten	< 20 ppm	Internal Ridaquick Gliadine kit (R-Biopharm AG) test
Residual gluten[2]	< 20 ppm	AOAC-OMA 2012.01

Abbreviations: ALOA-AES, Proprietary Agar for testing Listeria developed by AES Chemunex; AOAC, Association of Official Agricultural Chemists; BRD, Bio-Rad; cfu, colony forming units; EN, European norm; ELSD, Evaporating light scattering detector; HS, Head Space; IM, Internal Method; ISO, International Organization for Standardization; MA, Adapted method; n/a, not applicable; NF,

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French norm; NF V, French norm for food industry; OMA, Official Method of Analysis; RP-HPLC, reverse phase high performance liquid chromatography; TLC, thin layer chromatography
[1] Calculation based upon total nitrogen content.
[2]Analysis guaranteed under statistical control: minimum once a year.

Table 4. Ceramosides™ Powder Neutra Batch Analyses

Test Items	Specification	Lot# 21180709 Manufactured 07/09/2018	Lot# 21180702 Manufactured 07/02/2018	Lot# 21190307 Manufactured 03/07/2019	Method
Marker Compounds					
Total sphingolipids including glycosphingolipids	≥ 50%	66.4%	52.0%	56.8%	IM 06520-V3 (indirect[1])
DGDG	≥ 40%	41.3%	40.8%	41.3%	IM 06522-V4 (RP-HPLC, ELSD)
Total nitrogen linked to polar lipids	≥0.6%	0.8%	0.9%	0.8%	IM adapted from Dumas (combustion) NF EN ISO 16634-1 - 12/2008
Polar Lipids Identification[2]	Identical to Assay	Conforms	Conforms	Conforms	IM 06223-V3 (TLC)
Physical Characteristics					
Aspect	Thin powder	Conforms	Conforms	Conforms	Visual and Olfactive
Color	Beige to light brown	Conforms	Conforms	Conforms	
Odor	Cereal characteristic	Conforms	Conforms	Conforms	
Chemical Tests					

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Acid Value	<15 mg KOH/g	5.1 mg KOH/g	6.4 mg KOH/g	6.75 mg KOH/g	NF EN ISO 660-09/2009
Peroxide Value	<10 mEq/kg	< 0.1 mEq/kg	< 0.1 mEq/kg	<0.1 mEq/kg	NF EN ISO 3960-06/2010
Humidity	< 5%	1.0%	0.8%	0.7%	NF ISO 662-02/2001
Dry Extract	> 95%	99.0%	99.2%	99.3%	NF EN ISO 662-02/2001
Microbiological Tests					
Total aerobic plate count	≤ 100 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	NF EN ISO 4833-1-10/2013
Total Yeast & Mold	≤ 100 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	NF VO8-036-05/2003
Enterobacteria	Absent/g	Absent/g	Absent/g	Absent/g	NF ISO 21528.1-12/2014
Staphylococci coagulase + (37°C) including *Staphylococcus aureus*	Absent/g	Absent/g	Absent/g	Absent/g	NF EN ISO 6888.3-06/2003
Escherichia coli	Absent/g	Absent/g	Absent/g	Absent/g	Internal MA.104.4 adapted from ISO16649 .3
Salmonella	Absent/10 g	Absent/10 g	Absent/10 g	Absent/10 g	BRD 07/11-12/05
Listeria monocytogenes[2]	Absent/25 g	Absent/25 g	Absent/25 g	Absent/25 g	ALOA-AES 10/3-09/00
Heavy Metal Tests					

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Arsenic[2]	≤ 0.1 ppm	*	*	*	IM adapted from NF EN 15763 (ICP-MS)
Cadmium[2]	≤ 0.1 ppm	*	*	*	
Lead[2]	≤ 0.2 ppm	*	*	*	
Mercury[2]	≤ 0.1 ppm	*	*	*	
Solvent Analysis					
Acetone	< 30 ppm	< 5 ppm	< 5 ppm	< 5 ppm	Internal Method ref 06961_V2
Ethanol	< 5000 ppm	25 ppm	25 ppm	34 ppm	
Allergens					
Residual gluten	< 20 ppm	< 20 ppm	< 20 ppm	< 20 ppm	Internal Ridaquick Gliadine kit (R-Biopharm AG) test
Residual gluten[2]	< 20 ppm	< 20 ppm	< 20 ppm	< 20 ppm	AOAC-OMA 2012.01

Abbreviations: ALOA-AES, Proprietary Agar for testing Listeria developed by AES Chemunex; AOAC, Association of Official Agricultural Chemists; BRD, Bio-Rad; cfu, colony forming units; EN, European norm; ELSD, Evaporating light scattering detector; HS, Head Space; IM, Internal Method; ISO, International Organization for Standardization; MA, Adapted method; n/a, not applicable; NF, French norm; NF V, French norm for food industry; OMA, Official Method of Analysis; RP-HPLC, reverse phase high performance liquid chromatography; TLC, thin layer chromatography

[1] Calculation based upon total nitrogen content.

[2] Analysis guaranteed under statistical control: minimum once a year.

*Per [2], Heavy Metal Analysis is performed once a year and was not performed in this batch.

GRN 000907: On page 17 (Table 5) of the notice, SEPPIC provides heavy metal specifications for wheat seed oil and specifies an analytical method used to test for heavy metals. Please provide a statement that the specified analytical method has been validated for that particular purpose. SEPPIC also states that heavy metal analyses are performed once a year and, due to recent changes in specification limits, only two batch analyses have been tested to meet the specifications listed in Table 5. Please provide the results of these two batch analyses. If available, please provide the results of a third batch analysis. We would also suggest that SEPPIC include specifications for heavy metals in wheat seed oil and provide revised Tables 3 and 4 to reflect the specifications for heavy metals and the results of the batch analyses.

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Please find the attached statement verifying that the specified analytical methods have been validated for the purpose of heavy metal analysis. Additionally, 3 batches analyzing heavy metal results of the wheat seed oil are attached. Please find updated Table 3 which includes the heavy metal specification. Of the 3 shared heavy metal batch analyses, two are from batches that do not align with the batch numbers in Table 4. Therefore, their results were not added to Table 4.

Table 3. Ceramosides™ Oil Neutra Specifications

Test Items	Specification	Method
Marker Compounds		
Total sphingolipids including glycosphingolipids	≥ 15%	IM 06520-V3 (indirect[1])
DGDG	≥ 15%	IM 06522-V4 (RP-HPLC, ELSD)
Total Nitrogen linked with polar lipids	≥ 0.20%	IM adapted from Dumas (combustion) NF EN ISO 16634-1-12/2008
Polar Lipids Identification[2]	Identical to assay	IM 06223-V3 (TLC)
Physical Characteristics		
Aspect	Viscous oil	Visual and Olfactive
Color	Brown to light brown	
Odor	Cereal characteristic	
Chemical Data		
Acid Value	< 20 mg KOH/g	NF EN ISO 660-09/2009
Peroxide Value	< 10 mEq/kg	NF EN ISO 3960-06/2010
Density[2]	1.000± 0.030	IM 06224[3]
Humidity	< 5%	NF EN ISO 662-02/2001
Dry Extract	> 95%	NF EN ISO 662-02/2001
Microbiological Tests		
Total aerobic plate count	≤ 100 cfu/g	NF EN ISO 4833-1-10/2013

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Total Yeast & Mold	≤ 100 cfu/g	NF V08-036-05/2003
Enterobacteria	Absent/g	NF ISO 21528.1-12/2014
Staphylococci coagulase + (37°C) including *Staphylococcus aureus*	Absent/g	NF EN ISO 6888.3-06/2003
Escherichia coli	Absent/g	Internal MA 104.4 adapted from ISO16649.3
Salmonella	Absent/10 g	BRD 07/11-12/05
Listeria monocytogenes[2]	Absent/25 g	ALOA-AES 10/3-09/00
Heavy Metal Test		
Arsenic[2]	≤ 0.1 ppm	IM adapted from NF EN 15763 (ICP-MS)
Cadmium[2]	≤ 0.1 ppm	
Lead[2]	≤ 0.2 ppm	
Mercury[2]	≤ 0.1 ppm	
Solvent Analysis		
Ethanol	< 9000 ppm	Internal Method 06960_V1
Allergens		
Residual gluten	< 20 ppm	Internal Ridaquick Gliadine kit (R-Biopharm AG) test
Residual gluten[2]	< 20 ppm	AOAC-OMA 2012.01

Abbreviations: ALOA-AES, Proprietary Agar for testing Listeria developed by AES Chemunex; AOAC, Association of Official Agricultural Chemists; BRD, Bio-Rad; cfu, colony forming units; EN, European norm; ELSD, Evaporating light scattering detector; HS, Head Space; IM, Internal Method; ISO, International Organization for Standardization; MA, Adapted method; NF, French norm; NF V, French norm for food industry; OMA, Official Method of Analysis; RP-HPLC, reverse phase high performance liquid chromatography; TLC, thin layer chromatography

[1] Calculation based upon total nitrogen content.

[2] Analysis guaranteed under statistical control: minimum once a year.

[3] Calculation based on the determination of volumetric weight at 20ºC

Table 4. Ceramosides™ Oil Neutra Batch Analyses

Test Items	Specification	Lot # 411171219	Lot # 411190718	Lot # 411191223	Method

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		Manufactured 12/16/2017	Manufactured 07/18/2019	Manufactured 12/23/2019	
Marker Compounds					
Total sphingolipids including glyco-sphingolipids	≥ 15%	27.6%	18.3%	30.8%	IM 06520-V3 (indirect[1])
DGDG	≥ 15%	15.6%	23.0%	18.9%	IM 06522-V4 (RP-HPLC, ELSD)
Total Nitrogen linked with polar lipids	≥ 0.2%	0.36%	0.34%	0.3%	IM adapted from Dumas (combustion) NF EN ISO 16634-1-12/2008
Polar Lipids Identification[2]	Identical to assay	Conforms	Conforms	Conforms	IM 06223-V3 (TLC)
Physical Characteristics					
Aspect	Viscous oil	Conforms	Conforms	Conforms	Visual and olfactive
Color	Brown to light brown	Conforms	Conforms	Conforms	
Odor	Cereal characteristic	Conforms	Conforms	Conforms	
Chemical Tests					
Acid Value	< 20 mg KOH/g	11.6 mg KOH/g	11.6 mg KOH/g	13.1 KOH/g	NF ISO 660-09/2009
Peroxide Value	< 10 mEq/kg	< 0.1 mEq/kg	2.6 mEq/kg	< 0.1 mEq/kg	NF ISO 3960-06/2010
Density[2]	1.000± 0.030	Conforms	Conforms	Conforms	IM 06224[3]
Loss on drying	< 5%	1.7%	0.7%	0.9%	NF EN ISO 662-02/2001
Dry Extract	> 95%	98.3%	99.3%	98.1%	NF EN ISO 662-02/2001
Microbiological Tests					

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Total Aerobic Microbial	≤ 100 cfu/g	<10 cfu/g	<10 cfu/g	50 cfu/g	NF EN ISO 4833-1-10/2013
Total Yeast & Mold	≤ 100 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	NF V08-036-05/2003
Enterobacteria	Absent/g	Absent/g	Absent/g	Absent/g	NF ISO 21528.1-12/2014
Staphylococci coagulase + (37°C) including *Staphylococcus aureus*	Absent/g	Absent/g	Absent/g	Absent/g	NF ISO 6888.3-06/2003
Escherichia coli	Absent/g	Absent/g	Absent/g	Absent/g	Internal MA.104.4 adapted from ISO16649.3
Salmonella	Absent/10 g	Absent/10 g	Absent/10 g	Absent/10 g	BRD 07/11-12/05
Listeria monocytogenes[2]	Absent/25 g	Absent/25 g	Absent/25 g	Absent/25 g	ALOA-AES 10/3-09/00
Heavy Metal Tests					
Arsenic[2]	≤ 0.1 ppm	< 0.03 ppm	*	*	IM adapted from NF EN 15763 (ICP-MS)
Cadmium[2]	≤ 0.1 ppm	< 0.01 ppm	*	*	
Lead[2]	≤ 0.2 ppm	< 0.04 ppm	*	*	
Mercury[2]	≤ 0.1 ppm	< 0.05 ppm	*	*	
Solvent Analysis					
Ethanol	< 9000 ppm	9080 ppm**	6670 ppm	7515 ppm	Internal Method 06960_V1
Allergens					
Residual gluten	< 20 ppm	Conforms	Conforms	Conforms	Internal Ridaquick Gliadine kit (R-Biopharm AG) test

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Residual gluten[2]	< 20 ppm	Conforms	Conforms	Conforms	AOAC-OMA 2012.01

Abbreviations: ALOA-AES, Proprietary Agar for testing Listeria developed by AES Chemunex; AOAC, Association of Official Agricultural Chemists; BRD, Bio-Rad; cfu, colony forming units; EN, European norm; ELSD, Evaporating light scattering detector; HS, Head Space; IM, Internal Method; ISO, International Organization for Standardization; MA, Adapted method; n/a, not applicable; NF, French norm; NF V, French norm for food industry; OMA, Official Method of Analysis; RP-HPLC, reverse phase high performance liquid chromatography; TLC, thin layer chromatography

[1] Calculation based upon total nitrogen content.

[2] Analysis guaranteed under statistical control: minimum once a year.

[3] Calculation based on the determination of volumetric weight at 20ºC

*Per [2], Heavy Metal Analysis is performed once a year and was not performed in this batch

**This result conforms with the old specification of 20000 ppm. The specification was changed to 9000 ppm on 4/15/19.

6. **GRN 000906**: On page 17 of the notice, SEPPIC provides limits for residual ethanol (< 5000 ppm) and acetone (< 30 ppm), and states that analyses are performed on each batch of wheat seed polar lipids. Please specify methods used to test for residual solvents, provide a statement that these methods have been validated for that purpose, and provide results of three non-consecutive batch analyses to demonstrate that the ingredient meets the limits. We would also suggest that SEPPIC include specifications for residual ethanol and acetone in wheat seed polar lipids and provide revised Tables 3 and 4 to reflect the specifications for ethanol and acetone and the results of the batch analyses.
Please find the attached statement verifying that the specified analytical methods have been validated for the purpose of residual solvent analysis. Additionally, 3 batches analyzing residual solvent results of the wheat seed polar lipids are attached. The requested edits have been made to Table 3 and Table 4, updated in question 5 above.

GRN 000907: On page 17 of the notice, SEPPIC provides a limit for residual ethanol (< 9000 ppm) and states that analysis is performed on each batch of wheat seed oil. Please specify a method used to test for residual ethanol, provide a statement that this method has been validated for that purpose, and provide results of three non-consecutive batch analyses to demonstrate that the ingredient meets the limit. We would also suggest that SEPPIC include a specification for residual ethanol in wheat seed oil and provide revised Tables 3 and 4 to reflect the specification for ethanol and the results of the batch analyses.
Please find the attached statement verifying that the specified analytical methods have been validated for the purpose of residual solvent analysis. Additionally, 3 batches analyzing residual solvent results of the wheat seed oil are attached. The requested edits have been made to Table 3 and 4, updated in question 5 above.

7. **GRNs 000906 and 000907**: On page 19 (Table 6) of the notice, SEPPIC lists food categories in which the ingredient is intended to be used, including "Other functional beverages." The term "functional beverages" is ambiguous and may refer to several types of beverages, such as energy drinks, sport drinks, or nutrition drinks. Please clarify which food products SEPPIC considered in this food category.

As the intended uses for both GRNs have now been modified, only Ceramosides™ Powder Neutra (GRN 906) will be used in "functional beverages", and in fact, this will be its only intended use. NHANES food codes for beverages that contain functional ingredients were utilized as an assessment tool to estimate the exposure to the ingredient. Specifically, the following NHANES food codes were utilized in the analysis:

92582110 Fruit juice drink, added calcium (Sunny D)
92530410 Fruit flavored drink, with high vitamin C
92530510 Cranberry juice drink, with high vitamin C
92530610 Fruit juice drink, with high vitamin C
92530950 Vegetable and fruit juice drink, with high vitamin C
92582100 Fruit juice drink, with high vitamin C, plus added calcium
95310750 Energy drink (SoBe Energize Energy Juice Drink)
95312560 Energy drink (Ocean Spray Cran-Energy Juice Drink)

8. **GRN 000907**: On page 21 (Tables 7 and 8) of the notice, SEPPIC provides estimates of dietary exposure to wheat seed oil. We note that our dietary exposure assessment resulted in estimates lower than those provided by SEPPIC by approximately a factor of 10. Please address this discrepancy.

Due to the adjustments of the maximum intended addition levels in wheat seed polar lipids and wheat seed oil, this question is no longer applicable.

Toxicology:
Major deficiencies:
8. **Background:** The studies discussed in the notices are not published. The longest duration unpublished study is a 28-day study. Therefore, these studies cannot be used as corroborative evidence because there are no pivotal studies. The human studies were not designed to be tolerance or safety studies and are not useful in the context of the safety assessment of these ingredients.

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Comment to SEPPIC: The toxicological studies do not support the proposed use levels, which are ~350 mg/person (p)/day (d) for GRN 000906 and ~700 mg/p/d for GRN 000907. The basis for calculating the estimated daily intakes (EDIs) is not clear. The entire safety argument relies on lipid metabolism; however, safety arguments based entirely on metabolism of the ingredient do not help because the ingredients cannot be consumed endlessly. These ingredients are highly enriched (concentrated) from wheat in the final product, but consuming wheat is quite different from consuming high levels of these ingredients that normally exist in extremely minute quantities in wheat. Therefore, a strong safety rationale for supporting these use levels is necessary. Please provide a revised safety rationale to support the intended use levels.

Though wheat has been ingested by humans for millenia, it is true that a concentrated extract of wheat has not been commonly consumed by humans and therefore cannot have the presumption of safety. However, when the compositions of the wheat seed polar lipid and wheat seed oil are examined, they reveal various lipids, specifically sphingolipids and DGDG, that are commonly found across many food categories and have been shown to be safely and regularly consumed in average quantities in the United States. Sugawara et al., (1999) examined the quantity of DGDG in plant consumables using high performance liquid chromatography-evaporative light scattering detection (HPLC-ELSD).[4] Potočki et al., (2016) compared the quantity of sphingolipids in common dairy products, referencing, among others, Rombaut et al., (2005) that also used HPLC-ELSD to quantify sphingolipids.[5, 6] The data from these studies inform the relatively small additive quantity that would be augmented in consumers' diets with the ingestion of wheat seed polar lipid and wheat seed oil at the recommended amounts.

As discussed above, the new EDI for wheat seed polar lipid is 30 mg/person/day at the 90th percentile from certain functional beverages. Its composition is 50% sphingolipids, 40% DGDG, 5% water, and 5% triglycerides. Therefore, consumers would be exposed to approximately 15 mg of sphingolipids and 12 mg of DGDG with consumption of this ingredient in bars. Sugawara et al., showed that 100 g of steamed pumpkin (approximately 0.9 cup (https://fdc.nal.usda.gov/fdc-app.html#/food-details/168448/measures)) contains 68.6 mg of DGDG.[4] As consumption of wheat seed polar lipid at the 90th percentile exposure would provide 12.0 mg of DGDG, this would be equivalent to 17.5 g of steamed pumpkin (approximately 0.15 cup). Poločki et al. found that 100 g of skim milk (approximately 0.4 cup (https://fdc.nal.usda.gov/fdc-app.html#/food-details/781093/nutrients)) contains 6.0 mg of sphingolipids.[5] As consumption of wheat seed polar lipid at the EDI would provide 15.0 mg of sphingolipids, this would be equivalent to 250 g of skim milk (approximately 1 cup). Therefore, the addition of wheat seed polar lipids into the diet would be equivalent to 0.15 cup of steamed pumpkin and 1 cup of skim milk into the diet with regard to DGDG and sphingolipid content, respectively.

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The new EDI for wheat seed oil is 70 mg/p/day at the 90th percentile from bars. Its composition is 15% sphingolipids and 15% DGDG, as well as 10% phospholipids and 60% triglycerides. Therefore, consumers would be exposed to 10.5 mg of sphingolipids and 10.5 mg of DGDG with the estimated 90th percentile consumption of this product. As noted previously, in Sugawara et al., it was shown that 100 g of steamed pumpkin (approximately 0.9 cup)) has 68.6 mg of DGDG.[4] As consumption of wheat seed oil at the EDI would provide 10.5 mg of DGDG, this would be equivalent to 15.3 g of steamed pumpkin (approximately 0.13 cup). Again, as noted previously, Položki et al. revealed that 100 g of skim milk (approximately 0.4 cup) contains 6.0 mg of sphingolipids.[5] As consumption of wheat seed oil at the EDI would provide 10.5 mg of sphingolipids, this would be equivalent to the amount of sphingolipids found in 175 g of skim milk (approximately 0.72 cup). Therefore, the addition of wheat seed oil into the diet would be equivalent to 0.13 cup of steamed pumpkin and 0.72 cup of skim milk into the diet with regard to DGDG and sphingolipid content, respectively.

Sugawara et al. estimated the consumption of DGDG in Japan to be 220 mg/person/day[4] and Vesper et al. approximated the daily consumption of sphingolipids in the United states to be 300–400 mg/person/day.[7] Therefore, overall, consumption of wheat seed polar lipid at the 90th percentile would increase sphingolipid consumption by 3.8–5.0% and DGDG consumption by 5.5% percent and consumption of wheat seed oil at the 90th percentile would increase sphingolipid consumption 2.6–3.5% and DGDG consumption 4.7%. Therefore, overall, the increased exposure of the two constituents under the conditions of intended use is expected to be minimal.

9. **Background:** Daily dietary intake of all sphingolipids in adult humans is estimated to be ~ 300 mg or less. Clinical studies confirm a strong correlation between plasma and tissue levels of several ceramide species and insulin resistance. At the cellular level, ceramides have been shown to impair insulin signaling and intracellular handling of glucose and lipids with resulting deleterious effects on cellular metabolism. Circulating factors associated with obesity (*e.g.*, saturated fatty acids, inflammatory cytokines) selectively induce enzymes that promote sphingolipid synthesis, and lipidomic profiling reveals relationships between tissue sphingolipid levels and certain metabolic diseases. A variety of diabetic animal models, such as leptin-signaling deficient db/db mice and Zucker Diabetic fatty (ZDF) rats display profound changes in tissue sphingolipid levels. Also, in non-human primates, having developed diabetes due to persistent high-fat feeding, plasma levels of ceramide and dihydroceramide are elevated. Therefore, the relationship between elevated sphingolipid levels and the onset of hyperglycemic state holds true across various mammalian species studied.

a. **Please cite the upper safe limit of daily consumption of sphingolipids that has been reported in the published literature.** This is important because the metabolism of sphingolipids

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is not adequate to justify high exposure. Additionally, high levels of dietary sphingolipids can be digested and absorbed, but the constituents, at least in part, provide the base components for the re-synthesis of tissue sphingolipids and circulating sphingolipids (Vesper et al., 1999)].

We were unable to identify a published upper safe limit for sphingolipid consumption in the literature. However, it is reasonable to conclude the ingestion of the two wheat extracts at the new intended use levels would be safe considering the expected minor increases of overall sphingolipid consumption as outlined in question 8 and due to considerations reviewed in part b of this question.

b. **Please explain why the proposed additional use of sphingolipids would not be a concern for consumers.** The intended exposure to sphingolipids and digalactosyldiacylglycerol (DGDG), which is intimately tied to safety, makes the situation further complicated because of the overlap of food categories that will contain both wheat seed polar lipids and wheat seed oil, thereby further increasing the exposure. Please remember that we are not discussing consumers who are already in a hyperglycemic state; rather, we are concerned with consumers where excessive exposure to sphingolipids might trigger a transition into the hyperglycemic state.

The revised intended uses and exposure levels of the two wheat extracts have been described above. As previously stated, the revised exposure estimates suggest minor increases in total consumption of dietary sphingolipids and DGDG from the two wheat extracts, which are not likely to cause safety concerns. Even if an individual were to consume a bar and a beverage containing these ingredients (which is unlikely but possible), levels would still not significantly increase with regard to overall dietary intake.

Additionally, overall, there is sufficient contradictory data on sphingolipid consumption and insulin resistance[8-15] and inflammation[16-23] to suggest the data does not converge on a definitive conclusion about particular effects of exogenous sphingolipids on body tissues. Within the body, many forms of sphingolipids perform diametrically opposite cellular processes, which can complicate generalizations about this class of lipids.[17] Until more studies can adequately account for the disparate findings of the present studies on ceramides and its influence on inflammation and insulin resistance, recommendations on consumer consumption will remain ambiguous. Further explanation of these conclusions can be provided if desired.

Minor deficiencies:

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10.**GRNs 000906 and 000907**: On page 26 of the notice in Section 6.1.2 - Fate of sphingolipids, SEPPIC states "Germ-free mice show reduced hydrolysis of sphingomyelin resulting in 43% of sphingolipids excreted in feces (25-60% ceramide and 40-70% intact molecule) while non-germ-free mice were found to have only 25% excreted in feces (80-90% ceramide, 3-6% free sphingosine and 10% intact molecule)." (Reference # 11, Vesper et. al. 1999).
Comment: SEPPIC's statement regarding non-germ-free mice was not found in the reference cited, but was found in Nilsson (1968); however, the author used rats. Please check the references and correct the statements.

Thank you for pointing this out. The referenced citation (Vesper et al., 1999) was a review that referenced primary sources. Germ-free mice were referenced on pg 1242 (under the section Sphingolipid Digestion and Utilization and subsection: Hydrolysis of Sphingolipids in the Gastrointestinal Tract) and studies on germ-free mice were performed by Duan et al., 1995[24] and 1996[25], showing drastically reduced hydrolysis of sphingomyelin. However, the data in question, specifically 43% of sphingolipids excreted in feces (25-60% ceramide and 40-70% intact molecule), was cited from Nilsson 1968[26] and was incorrectly attributed to mice. This was due to the review article not specifying which animal was used in the Nilsson 1968 article. Therefore, the corrected statement should be "Germ-free mice showed reduced hydrolysis of sphingomyelin (Duan 1995 and 1996). Similarly, germ-free rats showed 43% of sphingolipids excreted in feces (25-60% ceramide and 40-70% intact molecule) while non-germ-free rats were found to have only 25% excreted in feces (80-90% ceramide, 3-6% free sphingosine and 10% intact molecule) (Nilsson 1968)."

11. **GRNs 000906 and 000907**: On page 26 of the notice in Section 6.1.2 - Fate of sphingolipids, SEPPIC states "Along with gastrointestinal microbiota, other factors that will impact hydrolysis and absorption include the amount of sphingomyelin absorbed, the presence of bile salts, and the levels of enzymes present." (Reference # 13, Nilsson and Duan. 2006). **Comment**: Please provide the section/page and paragraph where the involvement of microbiome in lipid hydrolysis and absorption has been discussed by Nilsson and Duan (2006). The preposition "along with gastrointestinal microbiota" was used to link the prior citation, which mentioned the effects of gastrointestinal microbiota on sphingomyelin digestion, with the comment about quantity of consumption, bile salt and enzymes.[27] The wording could be interpreted that the Nilsson and Dual citation referenced the gastrointestinal microbiota; however, the microbiota reference was referring to Vesper et al., (1999) (page 1242).[7]

12.**GRNs 000906 and 000907**: On page 35 in Section 6.6 - Past Sales and Reported Adverse Events, SEPPIC states "Additionally, according the manufacturer E.P.I France, no adverse events have been

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reported with respect to the ingredient following sales of 4126 kg of Ceramosides™ Powder Neutra from 1998-2019 in various countries." **Comment**: Please provide a reference to support this statement.

As in the US, reports of adverse events are published on products and ingredients that have reported adverse events. In France, the French agency ANSES (Agence Nationale de Securité Sanitaire de l'alimentation, de l'environement et du travail) reports adverse events through this process named "nutrivigilance". No ANSES reports on either of the CERAMOSIDE products have been located. Please see the signed statement.

13. Below is a theoretical exercise in determining the consumption of wheat seed polar lipids (GRN 000906).

A highly inflated consumption number is calculated below based on the statement made by SEPPIC on page 35 of the notice, **"4126 kg of Ceramosides™ Powder Neutra sold from 1998-2019."**
For this purpose, we made several assumptions as follows:
Assumption 1: 4126 kg Ceramosides™ Powder Neutra is ALL consumed by humans in ONE YEAR (**heavily inflated** consumption number).
Assumption 2: The number of people consuming this product is 1% of the French population (**heavily minimized** number of consumers).
Calculation: 4126 kg Ceramosides™ Powder Neutra consumed/year
= **(4126 x 106) mg** Ceramosides™ Powder Neutra consumed/year
France's population is ~65 million = 65 x 106 million people
1% of Frances's population = **65 x 104 million** people
Hence, individual consumption
= (4126 x 106) mg Ceramosides™ Powder Neutra consumed per year/65 x 104 million people
= 4126 x 102/65 = 6348 mg Ceramosides™ Powder Neutra consumed/p/year
= 6348 mg/365 = 17 mg Ceramosides™ Powder Neutra consumed/p/d (average).
It is clear that this (17 mg/p/d) is a heavily inflated consumption number. The true consumption number per person, even as a high-level consumer, would be far lower than this.
Please compare and comment on SEPPIC's proposed exposure (~350 mg/p/d for GRN 000906 and ~700 mg/p/d for GRN 000907) with this artificially inflated consumption number.

Even with the adjusted expected exposure to wheat seed polar lipids (Ceramosides™ Powder Neutra), consumers will likely ingest greater than the hypothetical calculated level of 17 mg of wheat seed polar lipids/p/day. Though it was noted that 4126 kg of Ceramosides™ Powder Neutra was sold from 1998–

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2019, this data was not meant to be pivotal data but instead to merely illustrate that the product has been present in the food system and no adverse events have thus far been reported.

Sincerely,

Kayla Preece, ND

Agent of the notifier
Scientific and Regulatory Consultant at AIBMR Life Sciences, Inc.

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ETHANOL RESIDUEL DANS CERAMOSIDES™ OIL NEUTRA
RESIDUAL ETHANOL IN CERAMOSIDES™ OIL NEUTRA

La teneur en éthanol résiduelle est déterminée selon la méthode suivante :
Residual ethanol content is determined with the following method:

Méthode de dosage / *Method of quantification*: méthode interne/*internal method* ref 06960_V1
Conditions HEAD SPACE CTS: HS500 / CTS: HS500
Température d'extration: 80°C / *temperature of extraction: 80°C*
Temps d'extraction: 20 min / *Time of extraction: 20 min*
Volume d'extraction: 1 ml / *Volume of extraction: 1 ml*
Conditions opératoires / *Operational conditions*
GC/FID, Agilent 5890
Colonne / *column* HP624 30 m Ø 0.32 mm, ep 1.8 µm + HP624 30 m Ø0.53 mm ep 3.0 µm
Pression tête de colonne / *head column pressure* : 7 psi
Gaz vecteur / *vector gaz* : H_2
Température du four / *hoven temperature* : 50 °C 5 min, 5°C/min jusqu'à / *until* 80°C, 25°C/min jusqu'à / *until* 220°C
Injecteur / *Injector* : 250 °C Splitless
Détecteur /*detector* : 300°C H_2 40ml/min

Limite de détection / *detection limit* : 0.50 g/kg

La méthode a été validée sur la matrice CERAMOSIDES™ OIL NEUTRA.
The method had been validated on the matrix CERAMOSIDES™ OIL NEUTRA.

La teneur en éthanol résiduel est garantie < 0.9 % pour tous les lots fabriqués à partir du 15/04/2019
Residual ethanol content is guaranted < 0.9 % for all batches produced from April 15th 2019

La quantification de l'éthanol résiduel dans le produit CERAMOSIDES™ OIL NEUTRA est réalisée en routine sur chaque lot.
Residual ethanol in CERAMOSIDES™ OIL NEUTRA is quantified routinely on each batch.

Pour information en annexe les résultats de dosage de l'éthanol résiduel sur 10 lots.
For information hereafter annexed, results of quantification of residual ethanol on 10 batches.

E.P.I. France - 3, rue de Préaux 02130 Villers sur Fère - FRANCE
Tél. : 33 (0)3.23.82.28.97 E-mail : v.bizot@epifrance.fr Site internet : www.epifrance.fr
SAS au capital de 45 000 € RCS SOISSONS B 414 332 817 SIRET : 414 332 817 00025 – APE : 1041 A – N° TVA FR 144 14 332 817

ETHANOL RESIDUEL DANS CERAMOSIDES™ OIL NEUTRA
RESIDUAL ETHANOL IN CERAMOSIDES™ OIL NEUTRA

ANNEXE

Residual ethanol content in 10 batches of CERAMOSIDES OIL NEUTRA as %
0.799
0.660
0.813
0.813
0.680
0.794
0.799
0.835
0.691
0.845

Fait à VILLERS SUR FERE,
Le 20/05/2020

Valérie BIZOT
Responsable Qualité / Quality Manager

E.P.I. France - 3, rue de Préaux 02130 Villers sur Fère - FRANCE
Tél. : 33 (0)3.23.82.28.97 E-mail : v.bizot@epifrance.fr Site internet : www.epifrance.fr
SAS au capital de 45 000 € RCS SOISSONS B 414 332 817 SIRET : 414 332 817 00025 – APE : 1041 A – N° TVA FR 144 14 332 817

Référence de la commande : 19-0469
Date de réception de l'échantillon : 30/12/2019
Version document : ENR-047-V1 du 04/01/2019

EPI France
Mme BIZOT Valérie
3 rue de Préaux
02130 VILLERS SUR FERE
FRANCE

BULLETIN D'ANALYSE N°: 51910

Ceramosides Oil Neutra - Lot 411191223

Recherche et quantification de composés par GC/FID

Nom du composé	Valeur mesurée (ppm)	Limite de quantification (ppm) *
Ethanol	7515	5000

* Dans les conditions opératoires

Saint Beauzire le 10/01/2020 13:36:00
Dr. Gilles FIGUERED
Directeur du laboratoir

Référence de la commande : 19-0278
Date de réception de l'échantillon : 24/07/2019
Version document : ENR-047-V1 du 04/01/2019

EPI France
Mme BIZOT Valérie
3 rue de Préaux
02130 VILLERS SUR FERE
FRANCE

BULLETIN D'ANALYSE N°: 48586

Ceramosides oil neutra - Lot 411190718

Recherche et quantification de composés par GC/FID

Nom du composé	Valeur mesurée (ppm)	Limite de quantification (ppm) *
Ethanol	6670	5000

* Dans les conditions opératoires

Saint Beauzire le 06/08/2019 10:11:00
Dr. Gilles FIGUERED
Directeur du laboratoi

EPI France
Mme BIZOT Valérie
3 rue de Préaux

02130 VILLERS SUR FERE
FRANCE

Document qualité n°: ENR-047 du 17/11/2010
Échantillon reçu au laboratoire le 21/12/2017
Date de commande / Vos références : N°17-0725

BULLETIN D'ANALYSE N°: 36893

Ceramosides oil neutra lot : 411171219 CHA

Recherche et quantification de composé par GC/FID

Nom du composé	Valeur mesurée en ppm	Limite de quantification en ppm *
Ethanol	9080	5000

* Dans les conditions opératoires

Saint Beauzire le : 08/01/2018 16:03:00
Dr. Gilles FIGUEREDO
Directeur du laboratoire

CERAMOSIDES™ POWDER NEUTRA
SOLVANTS RESIDUELS / *RESIDUAL SOLVENTS*

La teneur solvants résiduels (acétone et éthanol) est conforme avec la règlementation française et européenne en vigueur (Directive CE 88/344 et ses modifications, Arrêté du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires.)
Residual solvents content (acetone and ethanol) is conform to French and European regulatory in force (Directive CE 88/344 and its modifications, French decree of October 2006 concerning use of technological auxiliary in production of certain foodstuff.)

Méthode de dosage / *Method of quantification*: méthode interne/*internal method* ref 06961_V2
Conditions HEAD SPACE
CTS: HS500
Température d'extraction / *Temperature of extraction: 90°C*
Temps d'extraction / *Time of extraction : 20 min*
Volume d'extraction / *Volume of extraction : 1 ml*
GC/FID, Agilent 5890
Split 0.3
Colonne / *column* RTX624 30m Ø 0.32 mm, ep 1.8 µm
Pression tête de colonne / *head column pressure* : 7 psi
Gaz vecteur / *vector gaz* : H_2
Température du four / *hoven temperature* : 50 °C 5 min, 15°C/min jusqu'à / *until* 220°C
Injecteur / *Injector* : 250 °C
Détecteur /*detector* : 230°C H_2 40ml/min

Acétone résiduel / residual acetone : < 30 ppm
Ethanol résiduel / residual ethanol : < 5000 ppm

La méthode a été validée sur la matrice CERAMOSIDES™ POWDER NEUTRA
The method had been validated on the matrix CERAMOSIDES™ POWDER NEUTRA.

La quantification de l'acétone et de l'éthanol résiduel dans le produit CERAMOSIDES™ POWDER NEUTRA est réalisée en routine sur chaque lot.
Residual acetone and ethanol in CERAMOSIDES™ POWDER NEUTRA is quantified routinely on each batch.

Fait à VILLERS SUR FERE,
Le 20/05/2020

Valérie BIZOT
Quality Manager

Référence de la commande : n° 19-0083
Date de réception de l'échantillon : 13/03/2019
Version document : ENR-047-V1 du 04/01/2019

EPI France
Mme BIZOT Valérie
3 rue de Préaux
02130 VILLERS SUR FERE
FRANCE

BULLETIN D'ANALYSE N°: 45952

Ceramosides powder neutre - lot 21190307

Recherche et quantification de composés par Headspace/GC/FID

Nom du composé	Valeur mesurée (ppm)	Limite de quantification (ppm) *
Ethanol	34	5
Acétone	< LQ	5

* Dans les conditions opératoires

Saint Beauzire le 22/03
Dr. Gilles FIGUERED
Directeur du laboratoir

EPI France
Mme BIZOT Valérie
3 rue de Préaux
-
02130 VILLERS SUR FERE
FRANCE

Document qualité n°: ENR-047 du 17/11/2010
Échantillon reçu au laboratoire le 11/07/2018
Date de commande / Vos références : BdC n°18-0381

BULLETIN D'ANALYSE N°: 41075

Ceramosides powder neutra - lot 21180709CHA

Recherche et quantification de composés par Headspace/GC/FID

Nom du composé	Valeur mesurée en ppm	Limite de quantification en ppm *
Ethanol	25	5
Acétone	< LQ	5

* Dans les conditions opératoires

Saint Beauzire le : 23/07/2018 08:59:00
Dr. Gilles FIGUEREDO
Directeur du laboratoire

EPI France
Mme BIZOT Valérie
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-
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FRANCE

Document qualité n°: ENR-047 du 17/11/2010
Échantillon reçu au laboratoire le 04/07/2018
Date de commande / Vos références : BdC n° 18-0357

BULLETIN D'ANALYSE N°: 40909

Ceramosides Powder Neutra - lot 21180702CHA

Recherche et quantification de composés par Headspace/GC/FID

Nom du composé	Valeur mesurée en ppm	Limite de quantification en ppm *
Ethanol	25	5
Acétone	< LQ	5

* Dans les conditions opératoires

Saint Beauzire le : 23/07/2018 08:58:00
Dr. Gilles FIGUEREDO
Directeur du laboratoire

Phytocontrol AGRIFOOD

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EPI FRANCE
VALERIE BIZOT
3 RUE DE PREAUX
02130 VILLERS SUR FERE

Référence laboratoire	18/PN078233		
Référence client	Lot: 411171219 CHA		
Nature de l'échantillon	Ceramosides Oil Neutra	**Poids**	118,1g
Etat	Liquide	**Température à réception**	Ambiante
Date de réception	11/07/2018 09:57:23	**Limite de conservation**	11/08/2018
Echantillonnage	Client	**Transport**	TNT
Référence de devis	DPA180478	**Agence régionale**	Phytocontrol Paris_nord

Analyse demandée

Pesticides	1,4 Dichlorobenzene Liste spe PA170716/4 matrice grasse
Métaux lourds et ETM	Plomb Cadmium Arsenic Mercure Antimoine
Mycotoxines	Aflatoxines + Ochratoxine A + Deoxynivalenol (DON) + Zearalenone
Hydrocarbures aromatiques Polycycliques (HaP)	4 HAP

Echantillon à réception

Résultats d'analyses

	Résultat	Unité	LQ	Limite	Fin d'analyse
Pesticides					
Multirésidus GC 150					
2,4,6 trichlorophenol (TCP) (m)	0,036 ± 0,018	mg/kg	0,01		17/07/2018
Chlorpyrifos*	0,030 ± 0,009	mg/kg	0,01		17/07/2018
Chlorpyrifos-methyl*	0,57 ± 0,24	mg/kg	0,01		17/07/2018
Cypermethrine(α+β+θ+ζ)*	0,30 ± 0,11	mg/kg	0,01		17/07/2018
Deltamethrine*	0,64 ± 0,13	mg/kg	0,01		17/07/2018
Folpet(+Phtalimide)	0,067 ± 0,034	mg/kg			17/07/2018
Phtalimide	0,067 ± 0,034	mg/kg	0,01		17/07/2018
Piperonyl butoxide	6,3 ± 1,5	mg/kg	0,01	(1)	17/07/2018
Pirimiphos-methyl*	0,47 ± 0,19	mg/kg	0,01		17/07/2018
Liste 65 Californie numéro 1	ND				17/07/2018
Liste 65 Californie numéro 2	ND				17/07/2018
Monorésidus spécifiques					
Bromure de methyl CH3BR	ND	mg/kg	0,01		18/07/2018
1,3 dichloropropene	ND	mg/kg	0,01		18/07/2018
Dithiocarbamates (CS2)	ND	mg/kg	0,05		13/07/2018
Fentin (exprimé en cation triphenyletain)*	ND	mg/kg	0,01		16/07/2018
Nicotine	ND	mg/kg	0,01		12/07/2018
Pentachlorophenol	ND	mg/kg	0,01		24/07/2018
Métaux lourds et ETM					
Plomb*	< 0,04	mg/kg	0,04		12/07/2018
Cadmium*	< 0,01	mg/kg	0,01		12/07/2018
Arsenic*	< 0,03	mg/kg	0,03		12/07/2018
Mercure*	< 0,005	mg/kg	0,005		12/07/2018
Antimoine*	< 0,02	mg/kg	0,02		12/07/2018
Mycotoxines					
Aflatoxine B1	ND	µg/kg	1		12/07/2018
Aflatoxine B2	ND	µg/kg	1		12/07/2018
Aflatoxine G1	ND	µg/kg	1		12/07/2018
Aflatoxine G2	ND	µg/kg	1		12/07/2018
Aflatoxines (Σ B1,B2, G1,G2)	ND	µg/kg	1		12/07/2018
Ochratoxine A	ND	µg/kg	1		12/07/2018
Zearalenone	74 ± 14	µg/kg	10		12/07/2018
Deoxynivalenol	1003 ± 121	µg/kg	50		12/07/2018
Hydrocarbures aromatiques Polycycliques (HaP)					
Benzo(a)pyrene	6,5 ± 1,3	µg/kg	0,5		12/07/2018
Benzo(a)anthracene	8,1 ± 1,7	µg/kg	0,5		12/07/2018
Benzo(b)fluoranthene	8,3 ± 1,7	µg/kg	0,5		12/07/2018
Chrysene	8,3 ± 1,5	µg/kg	0,5		12/07/2018
Somme des 4 HAP	31 ± 6	µg/kg	0,5		12/07/2018
Autres contaminants					
1,4-Dichlorobenzene	ND	mg/kg	0,1		24/07/2018

Détail des paramètres analysés et des méthodes utilisées en page(s) suivante(s)

Légende

ND = Non détecté D = Détecté LQ = Limite de Quantification NA = Non Analysé
(m):dosé(s) sans son(ses) analyte(s) associé(s) pour les analyses de résidus pesticides effectuées uniquement dans le champs d'application du règlement N°396/2005 et ses modifications, ou des directives 2006/125/CE et 2006/141/CE, ou pour les analyses de résidus médicamenteux effectuées uniquement dans le champs d'application du règlement 37/2010 et du guide CRL/2007.
Méthodes utilisées mentionnées en page(s) suivante(s) :

Phytocontrol Analytics France, Parc Scientifique Georges BESSE II - 180 rue Philippe Maupas - CS 20009 - 30035 Nîmes Cedex 1
Tél. 04 34 14 70 00 - Fax. 04 66 23 99 95 - www.phytocontrol.com - contact@phytocontrol.com
S.A.S. au Capital de 1.000.000 euros - SIRET 490 024 049 00028 RCS Nîmes - TVA intracom FR08490024049 - APE 7120B

MOC3/06 version 0 : Détermination de la teneur en résidus de pesticides dans les produits gras d'origine végétale ou animale par GC-MS(n) : méthode interne.
MOC3/09 version 0 : Détermination de la teneur en bromure de méthyle dans les produits non gras d'origine végétale par GC-MS/HS : méthode interne.
MOC3/11 version 0 : Détermination des résidus de dithiocarbamates dans les produits d'origine végétale par GC-MS/HS : méthode interne.
MOC3/23 version 2 : Détermination de la teneur en HAP par GC-MS/MS : méthode interne.
MOC3/26 version 8 : Détermination de la teneur en résidus de pesticides dans les produits gras d'origine végétale et animale par GC-MS(n) : méthode interne.
MOC3/31 version 0 : Détermination de la teneur en organoétains dans les produits non gras d'origine végétale par LC-MS(n) : méthode interne.
MOC3/33 version 0 : Détermination de la teneur en nicotine dans les produits non gras d'origine végétale par LC-MS-MS : méthode interne.
MOC3/49 version 0 : Détermination de la teneur en 1,3-Dichloropropène dans les produits non gras d'origine végétale par GC-MS(n): méthode interne.
MOC3/68 version 0 : Détermination de la teneur en résidus de pesticides dans les produits d'origine végétale et animale par LC-MS(n): méthode interne.
MOC3/75 version 0 : Détermination de la teneur en 1, 1, 1, 2-Tetrafluoroethane, 1-Bromobutane, 1,2-Dichlorobenzene, 1,3-Dichlorobenzene et 1,4-Dichlorobenzenedans les produits d'origine végétale par GC-MS/HS: méthode interne.
MOC3/85 version 12 : Détermination de la teneur en métaux lourds et ETM (= Eléments Traces Métalliques) dans toutes denrées alimentaires d'origine animale ou végétale y compris la babyfood par ICP-MS: Méthode interne
MOC3111 version 2 : Détermination de la teneur en mycotoxines dans les produits d'origine végétale par LC-MS(n): méthode interne.
MOC3126 version 0 : Détermination de la teneur en pesticides par LC-MS(n) dans les produits gras d'origine végétale et animale : méthode interne

Commentaires

Les résultats analytiques ne sont valables que dans le périmètre du domaine d'application de la méthode utilisée.

Les valeurs limites indiquées sont issues des règlements et/ou des directives et/ou recommandations cités ci-dessous :

Pesticides

•Alimentation Humaine et Animale (matières premières) : Règlement (CE) N°396/2005 et ses modifications concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires et les aliments pour animaux d'origine végétale et animale.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Métaux lourds et ETM

•Alimentation Humaine :
Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
Cuivre et Mercure (selon matrice) : Règlement (CE) N°396/2005 et ses modifications concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires et les aliments pour animaux d'origine végétale et animale.
•Pour le vin : OIV - Limites maximales acceptables de divers éléments dans vin (édition 2015).
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.
•Additifs alimentaRèglement (UE) N°231/2012 et ses modifications successives établissant les spécifications des additifs alimentaires énumérés aux annexes II et III du règlement (CE) n°1333/2008 du Parlement européen et du Conseil.

Mycotoxines

•Alimentation Humaine :
- Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
- Recommandations 2013/165/UE concernant la présence de toxines T-2 et HT-2 dans les céréales et les produits à base de céréales.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Hydrocarbures aromatiques Polycycliques (HaP)

•Alimentation Humaine :
Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
Selon la matrice, les résultats sont exprimés en µg/kg (matière brute) ou en µg/kg MG (matière grasse).

-Le résultat du paramètre Benzo(a)anthracene est corrigé par le rendement d'extraction qui est de : 111%.
-Le résultat du paramètre Benzo(a)pyrene est corrigé par le rendement d'extraction qui est de : 114%.
-Le résultat du paramètre Benzo(b)fluoranthene est corrigé par le rendement d'extraction qui est de : 105%.
-Le résultat du paramètre Chrysene est corrigé par le rendement d'extraction qui est de : 110%.
-Le résultat du paramètre Deoxynivalenol ne tient pas compte du rendement d'extraction.
-Le résultat du paramètre Zearalenone ne tient pas compte du rendement d'extraction.

D'après les préconisations du laboratoire définies dans les conditions générales de vente, la quantité ou le nombre d'unité d'échantillon reçu n'est pas suffisant. Les analyses sont poursuivies sans incidence sur la validité des résultats, cependant la représentativité de l'échantillonnage pourrait, le cas échéant, ne pas suivre les exigences définies dans les règlements en vigueur.

(1) Le pipéronyl butoxide (PBO) est considéré comme un synergisant des pyrèthres naturels au niveau Européen, de ce fait aucune LMR communautaire n'est définie.
En revanche, pour les céréales cultivées en France, les autorités compétentes ont fixé une LMR nationale à 10mg/kg. Cette LMR ne s'applique pas aux céréales importées.
Dans le cadre de l'agriculture biologique, le CNAB (Comité National de l'Agriculture Biologique) a décidé dans sa réunion du 8 Décembre 2015, d'interdire toutes solutions phytosanitaires AB contenant du pipéronyl butoxyde sur le territoire français avec un délai de fin d'utilisation des stocks fixé au 30 Septembre 2017. En cas de détection en PBO, il convient de vous rapprocher de votre organisme certificateur.

informations complémentaires :
2,4,6 trichlorophenol (TCP) : Exprimé en Prochloraz.
Chlorpyrifos : = Chlorpyriphos-ethyl.
Cypermethrine(α+β+θ+ζ) : Somme des isomères.
Deltamethrine : Inclut cis-deltamethrine.
Folpet(+Phtalimide) : Somme du Folpet et du Phtalimide exprimée en folpet.
Phtalimide : Exprimé en Folpet.
Somme des 4 HAP : Somme de Benzo(a)pyrène, Benzo(a)anthracène, Benzo(b)fluoranthène et Chrysène.

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Signature

L'actualisation des données règlementaires est assurée par notre Service Veille Règlementaire dans le respect des dates de mise en application des textes européens ou autres référentiels publiés.

Rapport validé par :

Doriane BAUDOUIN
Validation Analytique

- Ce certificat produit et validé électroniquement fait foi. Le nom et la fonction des responsables sur ce document ont été produits sur base d'une procédure protégée et personnalisée. Une version papier de ce document paraphé peut être obtenue sur simple demande.
- Les résultats d'analyse ne concernent que les objets soumis à l'analyse.
- En l'absence de précision et d'indication contraire, la Limite de Détection est égale à la moitié de la Limite de Quantification (hors paramètres sous-traités).
- La reproduction de ce rapport n'est autorisée que sous sa forme intégrale sauf autorisation du laboratoire.
- Seules certaines prestations rapportées dans ce document sont couvertes par l'accréditation. Elles sont identifiées par le symbole *.
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Pesticides

Multirésidus GC 150

FB3/02.a vers. 20 (18/06/2018)

Unité ◦ : mg/kg	Résultat	LQ	méthode
2,4,6 trichlorophenol (TCP) (m	0,036	0,01	MOC3/06
2-Phenylphenol	ND	0,01	MOC3/06
4,4-Dichlorobenzophenone	ND	0,01	MOC3/06
Acetochlore	ND	0,01	MOC3/06
Acibenzolar-S-methyl (m)	ND	0,01	MOC3/06
Aclonifen*	ND	0,01	MOC3/26
Acrinathrine	ND	0,01	MOC3/06
Amisulbrom	ND	0,01	MOC3/06
Atrazine	ND	0,01	MOC3/06
Benalaxyl dont Benalaxyl-M*	ND	0,01	MOC3/26
Benfluraline	ND	0,01	MOC3/06
Bifenox	ND	0,01	MOC3/06
Bifenthrine (∑ des isomères)*	ND	0,01	MOC3/26
Biphenyl	ND	0,01	MOC3/06
Bromopropylate*	ND	0,01	MOC3/26
Butraline	ND	0,01	MOC3/06
Captan(+THPI)	ND		
Captan	ND	0,01	MOC3/06
Tetrahydrophtalimide (THPI	ND	0,01	MOC3/06
Carbofuran(somme) (m)	ND		
Carbofuran	ND	0,01	MOC3/06
Carbofuran-3-Hydroxy	ND	0,01	MOC3/06
Furathiocarbe	ND	0,01	MOC3/06
Carfentrazone-ethyl	ND	0,01	MOC3/06
Chlordane(cis+trans)	ND	0,01	MOC3/06
Chlorfenapyr	ND	0,01	MOC3/06
Chlorfenvinphos*	ND	0,01	MOC3/26
Chlorobenzilate	ND	0,01	MOC3/06
Chlorothalonil	ND	0,01	MOC3/06
Chlorprophame*	ND	0,01	MOC3/26
Chlorpyrifos*	0,030	0,01	MOC3/26
Chlorpyrifos-methyl*	0,57	0,01	MOC3/26
Clomazone	ND	0,01	MOC3/06
Coumaphos*	ND	0,01	MOC3/26
Cyfluthrine (β+γ)*	ND	0,01	MOC3/26
Cyhalofop-butyl	ND	0,01	MOC3/06
Cyhalothrine(lambda)*	ND	0,01	MOC3/26
Cypermethrine(α+β+θ+ζ)*	0,30	0,01	MOC3/26
Cyproconazole	ND	0,01	MOC3/06
Cyprodinil	ND	0,01	MOC3/06
DDT(somme)	ND		
o,p'-DDT	ND	0,01	MOC3/06
p,p'-DDT*	ND	0,01	MOC3/26
p,p'-DDE*	ND	0,01	MOC3/26
p,p'-TDE(DDD)	ND	0,01	MOC3/06
Deltamethrine*	0,64	0,01	MOC3/26
Dichlofenthion	ND	0,01	MOC3/06
Dichlorvos	ND	0,01	MOC3/06
Diclofop-methyl (m)	ND	0,01	MOC3/06
Dicofol(Σ des isomères)	ND		
Dicofol o,p'	ND	0,01	MOC3/06
Dicofol p,p'	ND	0,01	MOC3/06
Dieldrin(+Aldrin)	ND		
Dieldrin*	ND	0,01	MOC3/26
Aldrin	ND	0,01	MOC3/06
Diethofencarb	ND	0,01	MOC3/06
Difenoconazole	ND	0,01	MOC3/06
Diflufenican*	ND	0,01	MOC3/26
Diphenylamine	ND	0,01	MOC3/06
Endosulfan (somme)*	ND		
Endosulfan α*	ND	0,01	MOC3/26
Endosulfan β*	ND	0,01	MOC3/26
Endosulfan sulfate*	ND	0,01	MOC3/26
Ethion	ND	0,01	MOC3/06
Ethofumesate (m)	ND	0,01	MOC3/06
Ethoprophos	ND	0,01	MOC3/06
Ethoxyquine	ND	0,01	MOC3/06
Etofenprox	ND	0,01	MOC3/06
Etridiazole	ND	0,01	MOC3/06
Famoxadone	ND	0,01	MOC3/06
Fenamiphos (m)	ND	0,01	MOC3/06
Fenarimol	ND	0,01	MOC3/06
Fenazaquin	ND	0,01	MOC3/06
Fenhexamide	ND	0,01	MOC3/06
Fenitrothion*	ND	0,01	MOC3/26
Fenobucarbe	ND	0,01	MOC3/06
Fenpropathrine	ND	0,01	MOC3/06
Fenpropimorphe (∑ des isomères)	ND	0,01	MOC3/06
Fenvalerate (Σ des isomères)	ND	0,01	MOC3/06
Fipronil(somme)	ND		
Fipronil	ND	0,005	MOC3/06
Fipronil-sulfone	ND	0,005	MOC3/06
Fluazifop-p-butyl (m)	ND	0,01	MOC3/06
Fludioxonil*	ND	0,01	MOC3/26
Flufenacet (m)	ND	0,01	MOC3/06
Fluopicolide	ND	0,01	MOC3/06
Flurochloridone	ND	0,01	MOC3/06
Fluroxypyr-methylheptyl ester (m)	ND	0,01	MOC3/06
Flusilazole	ND	0,01	MOC3/06
Flutolanil	ND	0,01	MOC3/06
Flutriafol	ND	0,01	MOC3/06
Fluvalinate (Tau)*	ND	0,01	MOC3/26
Folpet(+Phtalimide)	0,067		
Folpet	ND	0,01	MOC3/06
Phtalimide	0,067	0,01	MOC3/06
Fonofos	ND	0,01	MOC3/06
Haloxyfop-2-ethoxyethyl (m)	ND	0,01	MOC3/06
Haloxyfop-methyl(R+S) (m)	ND	0,01	MOC3/06
HCB*	ND	0,01	MOC3/26
HCH(α+β+δ+e)	ND		
HCH alpha	ND	0,01	MOC3/06
HCH beta	ND	0,01	MOC3/06
HCH delta	ND	0,01	MOC3/06
HCH epsilon	ND	0,01	MOC3/06
HCH gamma	ND	0,01	MOC3/06
Heptachlore(somme)	ND		
Heptachlore	ND	0,01	MOC3/06
Heptachlore epoxyde cis-	ND	0,01	MOC3/06
Heptachlore epoxyde trans-	ND	0,01	MOC3/06
Iprodione	ND	0,01	MOC3/06
Malathion(+Malaoxon)	ND		
Malathion*	ND	0,01	MOC3/26
Malaoxon	ND	0,01	MOC3/06
Mepanipyrim	ND	0,01	MOC3/06
Metalaxyl dont Metalaxyl-M*	ND	0,01	MOC3/26
Metazachlor (m)	ND	0,01	MOC3/06
Methidathion*	ND	0,01	MOC3/26
Methoxychlore	ND	0,01	MOC3/06
Metolachlore dont S-Metolachlore	ND	0,01	MOC3/06
Myclobutanil*	ND	0,01	MOC3/26
Oxadiazon	ND	0,01	MOC3/06
Oxadixyl	ND	0,01	MOC3/06
Oxyfluorfene*	ND	0,01	MOC3/26
Penconazole	ND	0,01	MOC3/06
Pendimethaline	ND	0,01	MOC3/06
Permethrine(cis + trans)	ND	0,01	MOC3/06
Phosalone*	ND	0,01	MOC3/26
Piperonyl butoxide	6,3	0,01	MOC3/06
Pirimicarb	ND	0,01	MOC3/06
Pirimiphos-ethyl	ND	0,01	MOC3/06
Pirimiphos-methyl*	0,47	0,01	MOC3/26
Procymidone*	ND	0,01	MOC3/26
Profenophos	ND	0,01	MOC3/06
Prometryn	ND	0,01	MOC3/06
Propiconazole*	ND	0,01	MOC3/26
Propyzamide*	ND	0,01	MOC3/26
Proquinazid	ND	0,01	MOC3/06
Prosulfocarbe*	ND	0,01	MOC3/26
Pyridaben	ND	0,01	MOC3/06
Pyridalyl	ND	0,01	MOC3/06
Pyrimethanil	ND	0,01	MOC3/06
Pyriproxyfen	ND	0,01	MOC3/06
Quinoxyfen	ND	0,01	MOC3/06
Quintozene(+PCA)	ND		
Quintozene	ND	0,01	MOC3/06
Pentachloroaniline (PCA)	ND	0,01	MOC3/06
Quizalofop-ethyl	ND	0,01	MOC3/06
Tebuconazole*	ND	0,01	MOC3/26
Tebufenpyrad*	ND	0,01	MOC3/26
Tefluthrine*	ND	0,01	MOC3/26
Terbuthylazine	ND	0,01	MOC3/06
Tetramethrine*	ND	0,01	MOC3/26
Tolclofos-methyl	ND	0,01	MOC3/06
Tolylfluanid (m)	ND	0,01	MOC3/06
Triadimefon	ND	0,01	MOC3/06
Triadimenol	ND	0,01	MOC3/06
Triazophos	ND	0,01	MOC3/06
Trifluraline	ND	0,01	MOC3/06
Valifenalate	ND	0,01	MOC3/06
Vinclozoline	ND	0,01	MOC3/06
Zoxamide	ND	0,01	MOC3/06

Liste 65 Californie numéro 1

Unité ◦ : mg/kg	Résultat	LQ	méthode
Alachlore	ND	0,01	MOC3/06
Carbaryl	ND	0,01	MOC3/06
Diuron	ND	0,01	MOC3126
Fenoxycarbe	ND	0,01	MOC3126
Imazalil	ND	0,01	MOC3126
Methomyl	ND	0,01	MOC3126
Oryzalin	ND	0,01	MOC3126

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Propachlore (m)	ND	0,01	MOC3/06
Propargite	ND	0,01	MOC3126
Propoxur	ND	0,01	MOC3126
Thiodicarb	ND	0,01	MOC3126

Liste 65 Californie numéro 2

	Résultat	LQ	méthode
Unité ¤ : mg/kg			
2,4 DB (m)	ND	0,01	MOC3/68
Abamectine(somme)	ND		
Amitraze	ND	0,01	MOC3126
Bromacil	ND	0,01	MOC3126
Bromoxynil-octanoate	ND	0,01	MOC3/06
Carbendazime(+Benomyl)	ND	0,01	MOC3126
Cyanazine	ND	0,01	MOC3126
Oxydemeton-methyl	ND	0,01	MOC3126
Dinocap(Σ des isomères) (m)	ND	0,01	MOC3126
Dinoseb (m)	ND	0,01	MOC3126
EPTC	ND	0,01	MOC3126
Fenoxaprop-ethyl	ND	0,01	MOC3126
Fluazifop(acide libre) (m)	ND	0,01	MOC3126
Hydramethylnon	ND	0,01	MOC3126
Linuron	ND	0,01	MOC3126
Molinate	ND	0,01	MOC3126
Resmethrine	ND	0,01	MOC3126
Thiophanate-methyl	ND	0,01	MOC3126
Warfarin	ND	0,01	MOC3126

Monorésidus spécifiques

	Résultat	LQ	méthode
Unité ¤ : mg/kg			
Bromure de methyl CH3BR	ND	0,01	MOC3/09
1,3 dichloropropene	ND	0,01	MOC3/49
Dithiocarbamates (CS2)	ND	0,05	MOC3/11
Fentin (exprimé en cation triphenyletain)*	ND	0,01	MOC3/31
Nicotine	ND	0,01	MOC3/33
Pentachlorophenol	ND	0,01	MOC3/06

Métaux lourds et ETM

	Résultat	LQ	méthode
Unité ¤ : mg/kg			
Plomb*	< 0,04	0,04	MOC3/85
Cadmium*	< 0,01	0,01	MOC3/85
Arsenic*	< 0,03	0,03	MOC3/85
Mercure*	< 0,0050	0,005	MOC3/85
Antimoine*	< 0,02	0,02	MOC3/85

Mycotoxines

	Résultat	LQ	méthode
Unité ¤ : µg/kg			
Aflatoxine B1	ND	1	MOC3111
Aflatoxine B2	ND	1	MOC3111
Aflatoxine G1	ND	1	MOC3111
Aflatoxine G2	ND	1	MOC3111
Aflatoxines (Σ B1,B2, G1,G2)	ND	1	MOC3111
Ochratoxine A	ND	1	MOC3111
Zearalenone	74	10	MOC3111
Deoxynivalenol	1003	50	MOC3111

Hydrocarbures aromatiques Polycycliques (HaP)

	Résultat	LQ	méthode
Unité ¤ : µg/kg			
Benzo(a)pyrene	6,5	0,5	MOC3/23
Benzo(a)anthracene	8,1	0,5	MOC3/23
Benzo(b)fluoranthene	8,3	0,5	MOC3/23
Chrysene	8,3	0,5	MOC3/23
Somme des 4 HAP	31	0,5	MOC3/23

Autres contaminants

	Résultat	LQ	méthode
Unité ¤ : mg/kg			
1,4-Dichlorobenzene	ND	0,1	MOC3/75

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EPI FRANCE
VALERIE BIZOT
3 RUE DE PREAUX
02130 VILLERS SUR FERE

- Ce rapport annule et remplace la version précédente. Nous vous remercions de bien vouloir détruire la version précédente de ce rapport.

Référence laboratoire	16/PN41167		
Référence client	LOT 411160523 CHA		
Nature de l'échantillon	CERAMOSIDES OIL NEUTRA	**Poids**	108g
Etat	Liquide	**Température à réception**	Ambiante
Date de réception	27/06/2016 12:30:46	**Limite de conservation**	27/07/2016
Echantillonnage	Client	**Transport**	TNT
Référence de devis	DPA160330	**Agence régionale**	Phytocontrol Paris

Analyse demandée

Pesticides	Multirésidus GC 150
Métaux lourds et ETM	Plomb Cadmium Arsenic Mercure Antimoine
Mycotoxines	Aflatoxines + Ochratoxine A + Deoxynivalenol (DON) + Zearalenone
Autres contaminants	4 HAP

Echantillon à réception

Résultats d'analyses

	Résultat	Unité	LQ	Limite	Fin d'analyse
Pesticides					
Multirésidus GC 150					
Chlorpyrifos-methyl	1,1 ± 0,3	mg/kg	0,01		06/07/2016
Cypermethrine(α+β+θ+ζ)	1,4 ± 0,4	mg/kg	0,01		06/07/2016
Deltamethrine	2,1 ± 0,6	mg/kg	0,01		06/07/2016
Piperonyl butoxide	7,7 ± 1,8	mg/kg	0,01		06/07/2016
Pirimiphos-methyl	0,063 ± 0,032	mg/kg	0,01		06/07/2016
Tebuconazole	0,17 ± 0,09	mg/kg	0,01		06/07/2016
Métaux lourds et ETM					
Plomb*	< 0,04	mg/kg	0,04		29/06/2016
Cadmium*	< 0,01	mg/kg	0,01		29/06/2016
Arsenic*	< 0,03	mg/kg	0,03		29/06/2016
Mercure*	< 0,005	mg/kg	0,005		29/06/2016
Antimoine*	< 0,02	mg/kg	0,02		29/06/2016
Mycotoxines					
Aflatoxine B1	ND	µg/kg	2		30/06/2016
Aflatoxines (Σ B1,B2, G1,G2)	ND	µg/kg	8		30/06/2016
Ochratoxine A	2,5 ± 0,7	µg/kg	2		30/06/2016
Zearalenone	ND	µg/kg	10		30/06/2016
Deoxynivalenol	ND	µg/kg	50		30/06/2016
Hydrocabures aromatiques Polycliques (HaP)					
Somme des 4 HAP	5,6 ± 1	µg/kg	0,5		29/06/2016
Benzo(a)anthracene*	1,2 ± 0,3	µg/kg	0,5		29/06/2016
Benzo(a)pyrene*	0,90 ± 0,2	µg/kg	0,5		29/06/2016
Benzo(b)fluoranthene	1,2 ± 0,2	µg/kg	0,5		29/06/2016
Chrysene*	2,3 ± 0,3	µg/kg	0,5		29/06/2016

Détail des paramètres analysés et des méthodes utilisées en page(s) suivante(s)

Légende

ND = Non détecté D = Détecté LQ = Limite de Quantification NA = Non Analysé

Méthodes utilisées mentionnées en page(s) suivante(s) :

MOC3/06 version 0 : Détermination de la teneur en résidus de pesticides dans les produits gras d'origine végétale ou animale par GC-MS(n) : méthode interne.

MOC3/14 version 0 : Détermination de la teneur en HAP par GC-MS(n) et/ou UFLC : méthode interne.

MOC3/28 version 2 : Détermination de la teneur en HAP par GC-MS(n) : méthode interne.

MOC3/85 version 9 : Détermination de la teneur en métaux lourds et ETM (= Eléments Traces Métalliques) dans toutes denrées alimentaires d'origine animale ou végétale y compris la babyfood par ICP-MS: Méthode interne

MOC3111 version 2 : Détermination de la teneur en mycotoxines dans les produits d'origine végétale par UFLC: méthode interne.

Commentaires

Les valeurs limites indiquées sont issues des règlements et/ou des directives et/ou recommandations cités ci-dessous :

Pesticides

•Alimentation Humaine et Animale (matières premières) : Règlement (CE) N°396/2005 et ses modifications concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires et les aliments pour animaux d'origine végétale et animale.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Métaux lourds et ETM

•Alimentation Humaine :
Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
•Pour le vin : OIV - Limites maximales acceptables de divers éléments dans vin (édition 2015).
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Mycotoxines

•Alimentation Humaine :
- Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
- Recommandations 2013/165/UE concernant la présence de toxines T-2 et HT-2 dans les céréales et les produits à base de céréales.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Hydrocabures aromatiques Polycliques (HaP)

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Signature

Rapport validé par : Céline CEZAR
Veille Réglementaire et Sécurité Alimentaire

David SANCHEZ

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- Ce rapport annule et remplace le rapport précédent.

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Pesticides

Multirésidus GC 150

FB3/02.a vers. 10 (02/05/2016)

Unité ⇩ : mg/kg	Résultat	LQ	méthode
2-Phenylphenol	ND	0,01	MOC3/06
3,4-dichloroaniline	ND	0,01	MOC3/06
4,4-Dichlorobenzophenone	ND	0,01	MOC3/06
Acibenzolar-S-methyl	ND	0,01	MOC3/06
Aclonifen	ND	0,01	MOC3/06
Acrinathrine	ND	0,01	MOC3/06
Atrazine	ND	0,01	MOC3/06
Benalaxyl dont Benalaxyl-M	ND	0,01	MOC3/06
Benfluraline	ND	0,01	MOC3/06
Bifenox	ND	0,01	MOC3/06
Bifenthrine	ND	0,01	MOC3/06
Biphenyl	ND	0,01	MOC3/06
Bitertanol	ND	0,01	MOC3/06
Bromopropylate	ND	0,01	MOC3/06
Butachlor	ND	0,01	MOC3/06
Butraline	ND	0,01	MOC3/06
Captan	ND	0,01	MOC3/06
Carbofuran(+3-hydroxy)+Furathiocarb	ND	0,01	MOC3/06
Carfentrazone-ethyl	ND	0,01	MOC3/06
Chlordane(cis+trans)	ND	0,01	MOC3/06
Chlorfenvinphos	ND	0,01	MOC3/06
Chlorobenzilate	ND	0,01	MOC3/06
Chlorothalonil	ND	0,01	MOC3/06
Chlorprophame	ND	0,01	MOC3/06
Chlorpyrifos	ND	0,01	MOC3/06
Chlorpyrifos-methyl	1,1	0,01	MOC3/06
Chlorthal dimethyl	ND	0,01	MOC3/06
Clomazone	ND	0,01	MOC3/06
Coumaphos	ND	0,01	MOC3/06
Cyfluthrine (β+γ)	ND	0,01	MOC3/06
Cyhalofop-butyl	ND	0,01	MOC3/06
Cyhalothrine(lambda)	ND	0,01	MOC3/06
Cymiazole	ND	0,01	MOC3/06
Cypermethrine(α+β+θ+ζ)	1,4	0,01	MOC3/06
Cyproconazole	ND	0,01	MOC3/06
Cyprodinil	ND	0,01	MOC3/06
DDT(Σ des isomères)	ND	0,01	MOC3/06
Deltamethrine	2,1	0,01	MOC3/06
Diazinon	ND	0,01	MOC3/06
Dichlofenthion	ND	0,01	MOC3/06
Dichlorvos	ND	0,01	MOC3/06
Diclofop-methyl	ND	0,01	MOC3/06
Dicofol(Σ des isomères)	ND	0,01	MOC3/06
Dieldrin(+Aldrin)	ND	0,01	MOC3/06
Diethofencarb	ND	0,01	MOC3/06
Difenoconazole	ND	0,01	MOC3/06
Diflufenican	ND	0,01	MOC3/06
Diphenylamine	ND	0,01	MOC3/06
Endosulfan (α+β+sulfate)	ND	0,01	MOC3/06
Ethion	ND	0,01	MOC3/06
Ethofumesate	ND	0,01	MOC3/06
Ethoprophos	ND	0,01	MOC3/06
Ethoxyquine	ND	0,01	MOC3/06
Etofenprox	ND	0,01	MOC3/06
Etridiazole	ND	0,01	MOC3/06
Famoxadone	ND	0,01	MOC3/06
Fenamiphos	ND	0,01	MOC3/06
Fenarimol	ND	0,01	MOC3/06
Fenazaquin	ND	0,01	MOC3/06
Fenchlorphos(+oxon)	ND	0,01	MOC3/06
Fenhexamide	ND	0,01	MOC3/06
Fenitrothion	ND	0,01	MOC3/06
Fenoxaprop-ethyl	ND	0,01	MOC3/06
Fenoxycarbe	ND	0,01	MOC3/06
Fenpropathrine	ND	0,01	MOC3/06
Fenpropidine	ND	0,01	MOC3/06
Fenpropimorphe	ND	0,01	MOC3/06
Fenthion(+sulfone+sulfoxide)	ND	0,01	MOC3/06
Fenvalerate (Σ des isomères)	ND	0,01	MOC3/06
Fipronil(+sulfone)	ND	0,005	MOC3/06
Fipronil-desulfinyl	ND	0,01	MOC3/06
Fluazifop-p-butyl	ND	0,01	MOC3/06
Flucythrinate	ND	0,01	MOC3/06
Fludioxonil	ND	0,01	MOC3/06
Flufenacet	ND	0,01	MOC3/06
Fluopicolide	ND	0,01	MOC3/06
Flurochloridone	ND	0,01	MOC3/06
Fluroxypyr-methylheptyl ester	ND	0,01	MOC3/06
Flusilazole	ND	0,01	MOC3/06
Flutolanil	ND	0,01	MOC3/06
Flutriafol	ND	0,01	MOC3/06
Fluvalinate (Tau)	ND	0,01	MOC3/06
Folpet	ND	0,01	MOC3/06
Fonofos	ND	0,01	MOC3/06
Haloxyfop-2-ethoxyethyl	ND	0,01	MOC3/06
Haloxyfop-methyl(R+S)	ND	0,01	MOC3/06
HCB	ND	0,01	MOC3/06
HCH gamma	ND	0,01	MOC3/06
HCH(α+β+δ)	ND	0,01	MOC3/06
Heptachlore(+epoxyde)	ND	0,01	MOC3/06
Hexaconazole	ND	0,01	MOC3/06
Iprodione	ND	0,01	MOC3/06
Isoxadifen-ethyl	ND	0,01	MOC3/06
Isoxaflutole	ND	0,01	MOC3/06
Malathion(+Malaoxon)	ND	0,01	MOC3/06
Mepanipyrim	ND	0,01	MOC3/06
Metalaxyl dont Metalaxyl-M	ND	0,01	MOC3/06
Metazachlor	ND	0,01	MOC3/06
Methidathion	ND	0,01	MOC3/06
Methiocarbe	ND	0,01	MOC3/06
Methoxychlore	ND	0,01	MOC3/06
Metolachlore dont S-Metolachlore	ND	0,01	MOC3/06
Metribuzine	ND	0,01	MOC3/06
Monalide	ND	0,01	MOC3/06
Myclobutanil	ND	0,01	MOC3/06
Napropamide	ND	0,01	MOC3/06
Oxadiazon	ND	0,01	MOC3/06
Oxadixyl	ND	0,01	MOC3/06
Oxyfluorfene	ND	0,01	MOC3/06
Parathion-ethyl	ND	0,01	MOC3/06
Parathion-methyl	ND	0,01	MOC3/06
Penconazole	ND	0,01	MOC3/06
Pendimethaline	ND	0,01	MOC3/06
Permethrine(cis + trans)	ND	0,01	MOC3/06
Phosalone	ND	0,01	MOC3/06
Piperonyl butoxide	7,7	0,01	MOC3/06
Pirimicarb	ND	0,01	MOC3/06
Pirimiphos-ethyl	ND	0,01	MOC3/06
Pirimiphos-methyl	0,063	0,01	MOC3/06
Prochloraz(+TCP)	ND	0,01	MOC3/06
Procymidone	ND	0,01	MOC3/06
Profenophos	ND	0,01	MOC3/06
Propiconazole	ND	0,01	MOC3/06
Propyzamide	ND	0,01	MOC3/06
Proquinazid	ND	0,01	MOC3/06
Prosulfocarbe	ND	0,01	MOC3/06
Pyridaben	ND	0,01	MOC3/06
Pyridalyl	ND	0,01	MOC3/06
Pyridaphenthion	ND	0,01	MOC3/06
Pyrimethanil	ND	0,01	MOC3/06
Pyriproxyfen	ND	0,01	MOC3/06
Quinoxyfen	ND	0,01	MOC3/06
Quintozene(+PCA)	ND	0,01	MOC3/06
Quizalofop-ethyl	ND	0,01	MOC3/06
S 421	ND	0,01	MOC3/06
Sebuthylazine	ND	0,01	MOC3/06
Tebuconazole	0,17	0,01	MOC3/06
Tebufenpyrad	ND	0,01	MOC3/06
Tebupirimphos	ND	0,01	MOC3/06
Tefluthrine	ND	0,01	MOC3/06
Terbufos	ND	0,01	MOC3/06
Terbuthylazine	ND	0,01	MOC3/06
Tetramethrine	ND	0,01	MOC3/06
Tolclofos-methyl	ND	0,01	MOC3/06
Tolylfluanid	ND	0,01	MOC3/06
Triadimefone+Triadimenol	ND	0,01	MOC3/06
Triazophos	ND	0,01	MOC3/06
Trifluraline	ND	0,01	MOC3/06
Valifenalate	ND	0,01	MOC3/06
Vinclozoline	ND	0,01	MOC3/06
Zoxamide	ND	0,01	MOC3/06

Métaux lourds et ETM

Unité ⇩ : mg/kg	Résultat	LQ	méthode
Plomb*	< 0,04	0,04	MOC3/85
Cadmium*	< 0,01	0,01	MOC3/85
Arsenic*	< 0,03	0,03	MOC3/85
Mercure*	< 0,005	0,005	MOC3/85
Antimoine*	< 0,02	0,02	MOC3/85

Mycotoxines

Unité ⇩ : µg/kg	Résultat	LQ	méthode
Aflatoxine B1	ND	2	MOC3111
Aflatoxines (Σ B1,B2, G1,G2)	ND	8	MOC3111
Ochratoxine A	2,5	2	MOC3111
Zearalenone	ND	10	MOC3111
Deoxynivalenol	ND	50	MOC3111

Hydrocabures aromatiques Polycliques (HaP)

	Résultat	LQ	méthode

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Somme des 4 HAP	5,6	0,5	MOC3/14
Benzo(a)anthracene*	1,2	0,5	MOC3/28
Benzo(a)pyrene*	0,90	0,5	MOC3/28
Benzo(b)fluoranthene	1,2	0,5	MOC3/14
Chrysene*	2,3	0,5	MOC3/28

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EPI FRANCE
VALERIE BIZOT
3 RUE DE PREAUX
02130 VILLERS SUR FERE

Référence laboratoire	15/PN77832		
Référence client	lot 411151210 EUR		
Nature de l'échantillon	ceramosides oil neutra	**Poids**	75g
Etat	Liquide	**Température à réception**	Ambiante
Date de réception	24/12/2015 12:59:24	**Limite de conservation**	24/01/2016
Echantillonnage	Client	**Transport**	TNT
Référence de devis	DPA150359	**Agence régionale**	Phytocontrol Paris

Analyse demandée

Pesticides	Multirésidus GC 150
Métaux lourds et ETM	Plomb Cadmium Arsenic Mercure Antimoine
Mycotoxines	Aflatoxines + Ochratoxine A + Deoxynivalenol (DON) + Zearalenone

Echantillon à réception

Résultats d'analyses

	Résultat	Unité	LQ	Limite	Fin d'analyse
Pesticides					
Multirésidus GC 150					
Chlorprophame(+3-Chloroaniline)	0,027 ± 0,014	mg/kg	0,01		06/01/2016
Chlorpyrifos-methyl	0,64 ± 0,22	mg/kg	0,01		06/01/2016
Deltamethrine	0,80 ± 0,3	mg/kg	0,01		06/01/2016
Piperonyl butoxide	4,5 ± 1,1	mg/kg	0,01		06/01/2016
Pirimiphos-methyl	0,030 ± 0,015	mg/kg	0,01		06/01/2016
Tebuconazole	0,11 ± 0,06	mg/kg	0,01		06/01/2016
Métaux lourds et ETM					
Plomb	< 0,04	mg/kg	0,04		29/12/2015
Cadmium	< 0,01	mg/kg	0,01		29/12/2015
Arsenic	< 0,03	mg/kg	0,03		29/12/2015
Mercure	< 0,005	mg/kg	0,005		29/12/2015
Antimoine	< 0,02	mg/kg	0,02		29/12/2015
Mycotoxines					
Aflatoxine B1	ND	µg/kg	2		29/12/2015
Aflatoxines (Σ B1,B2, G1,G2)	ND	µg/kg	8		29/12/2015
Ochratoxine A	ND	µg/kg	2		29/12/2015
Zearalenone	ND	µg/kg	10		29/12/2015
Deoxynivalenol	ND	µg/kg	50		29/12/2015

Détail des paramètres analysés et des méthodes utilisées en page(s) suivante(s)

Légende

ND = Non détecté D = Détecté LQ = Limite de Quantification NA = Non Analysé

Méthodes utilisées mentionnées en page(s) suivante(s) :

MOC3/06 version 0 : Détermination de la teneur en résidus de pesticides dans les produits gras d'origine végétale ou animale par GC-MS(n) : méthode interne.

MOC3/92 version 7 : Détermination de la teneur en métaux lourds et ETM (= Eléments Traces Métalliques) dans toutes denrées alimentaires d'origine animale ou végétale y compris la babyfood par ICP-MS: Méthode interne

MOC3111 version 2 : Détermination de la teneur en mycotoxines dans les produits d'origine végétale par UFLC: méthode interne.

Commentaires

Les valeurs limites indiquées sont issues des règlements et/ou des directives et/ou recommandations cités ci-dessous :

Pesticides

•Alimentation Humaine et Animale (matières premières) : Règlement (CE) N°396/2005 et ses modifications concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires et les aliments pour animaux d'origine végétale et animale.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Métaux lourds et ETM

•Alimentation Humaine :
Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
•Pour le vin : OIV - Limites maximales acceptables de divers éléments dans vin (édition 2015).
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Mycotoxines

•Alimentation Humaine :
- Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
- Recommandations 2013/165/UE concernant la présence de toxines T-2 et HT-2 dans les céréales et les produits à base de céréales.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

informations complémentaires :

Chlorprophame(+3-Chloroaniline) : = CIPC. Somme du Chlorprophame et de la 3-Chloroaniline exprimée en Chlorprophame.

Deltamethrine : Inclut cis-deltamethrine.

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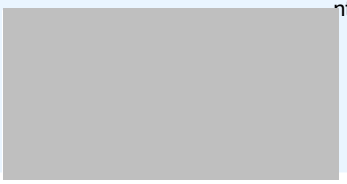
Signature

Rapport validé par : Julie DEGOUL Séverine DELAYE

Veill ntaire



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- Les résultats d'analyse ne concernent que les objets soumis à l'analyse.
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Pesticides

Multirésidus GC 150

FB3/02.a vers. (30/01/2015)

	Résultat	LQ	méthode
Unité ⇩ : mg/kg			
2-Phenylphenol	ND	0,01	MOC3/06
3,4-dichloroaniline	ND	0,01	MOC3/06
Acibenzolar-S-methyl	ND	0,01	MOC3/06
Aclonifen	ND	0,01	MOC3/06
Acrinathrine	ND	0,01	MOC3/06
Atrazine	ND	0,01	MOC3/06
Benalaxyl dont Benalaxyl-M	ND	0,01	MOC3/06
Benfluraline	ND	0,01	MOC3/06
Bifenox	ND	0,01	MOC3/06
Bifenthrine	ND	0,01	MOC3/06
Biphenyl	ND	0,01	MOC3/06
Bitertanol	ND	0,01	MOC3/06
Bromopropylate	ND	0,01	MOC3/06
Butachlor	ND	0,01	MOC3/06
Butraline	ND	0,01	MOC3/06
Captan	ND	0,01	MOC3/06
Carbofuran(+3-hydroxy)	ND	0,01	MOC3/06
Carfentrazone-ethyl	ND	0,01	MOC3/06
Chlordane(cis+trans)	ND	0,01	MOC3/06
Chlorfenvinphos	ND	0,01	MOC3/06
Chlorobenzilate	ND	0,01	MOC3/06
Chlorothalonil	ND	0,01	MOC3/06
Chlorprophame(+3-Chloroaniline)	0,027	0,01	MOC3/06
Chlorpyrifos	ND	0,01	MOC3/06
Chlorpyrifos-methyl	0,64	0,01	MOC3/06
Chlorthal dimethyl	ND	0,01	MOC3/06
Clomazone	ND	0,01	MOC3/06
Coumaphos	ND	0,01	MOC3/06
Cyfluthrine (β+γ)	ND	0,01	MOC3/06
Cyhalofop-butyl	ND	0,01	MOC3/06
Cyhalothrine(lambda)	ND	0,01	MOC3/06
Cymiazole	ND	0,01	MOC3/06
Cypermethrine(α+β+θ+ζ)	ND	0,01	MOC3/06
Cyproconazole	ND	0,01	MOC3/06
Cyprodinil	ND	0,01	MOC3/06
DDT(Σ des isomères)	ND	0,01	MOC3/06
Deltamethrine	0,80	0,01	MOC3/06
Diazinon	ND	0,01	MOC3/06
Dichlofenthion	ND	0,01	MOC3/06
Diclofop-methyl	ND	0,01	MOC3/06
Dicofol(Σ des isomères)	ND	0,01	MOC3/06
Dieldrin(+Aldrin)	ND	0,01	MOC3/06
Diethofencarb	ND	0,01	MOC3/06
Difenoconazole	ND	0,01	MOC3/06
Diflufenican	ND	0,01	MOC3/06
Diphenylamine	ND	0,01	MOC3/06
Endosulfan (α+β+sulfate)	ND	0,01	MOC3/06
Ethion	ND	0,01	MOC3/06
Ethofumesate	ND	0,01	MOC3/06
Ethoprophos	ND	0,01	MOC3/06
Ethoxyquine	ND	0,01	MOC3/06
Etofenprox	ND	0,01	MOC3/06
Etridiazole	ND	0,01	MOC3/06
Famoxadone	ND	0,01	MOC3/06
Fenamiphos	ND	0,01	MOC3/06
Fenarimol	ND	0,01	MOC3/06
Fenazaquin	ND	0,01	MOC3/06
Fenchlorphos(+oxon)	ND	0,01	MOC3/06
Fenhexamide	ND	0,01	MOC3/06
Fenitrothion	ND	0,01	MOC3/06
Fenoxaprop-ethyl	ND	0,01	MOC3/06
Fenoxycarbe	ND	0,01	MOC3/06
Fenpropathrine	ND	0,01	MOC3/06
Fenpropidine	ND	0,01	MOC3/06
Fenpropimorphe	ND	0,01	MOC3/06
Fenthion(+sulfone+sulfoxide)	ND	0,01	MOC3/06
Fenvalerate (Σ des isomères)	ND	0,01	MOC3/06
Fipronil(+sulfone)	ND	0,005	MOC3/06
Fipronil-desulfinyl	ND	0,01	MOC3/06
Fluazifop-p-butyl	ND	0,01	MOC3/06
Flucythrinate	ND	0,01	MOC3/06
Fludioxonil	ND	0,01	MOC3/06
Flufenacet	ND	0,01	MOC3/06
Fluopicolide	ND	0,01	MOC3/06
Flurochloridone	ND	0,01	MOC3/06
Fluroxypyr-methylheptyl ester	ND	0,01	MOC3/06
Flusilazole	ND	0,01	MOC3/06
Flutolanil	ND	0,01	MOC3/06
Flutriafol	ND	0,01	MOC3/06
Fluvalinate (Tau)	ND	0,01	MOC3/06
Folpet	ND	0,01	MOC3/06
Fonofos	ND	0,01	MOC3/06
Haloxyfop-2-ethoxyethyl	ND	0,01	MOC3/06
Haloxyfop-methyl(R+S)	ND	0,01	MOC3/06
HCB	ND	0,01	MOC3/06
HCH gamma	ND	0,01	MOC3/06
HCH(α+β+δ)	ND	0,01	MOC3/06
Heptachlore(+epoxyde)	ND	0,01	MOC3/06
Hexaconazole	ND	0,01	MOC3/06
Iprodione	ND	0,01	MOC3/06
Isoxadifen-ethyl	ND	0,01	MOC3/06
Isoxaflutole	ND	0,01	MOC3/06
Malathion(+Malaoxon)	ND	0,01	MOC3/06
Mepanipyrim	ND	0,01	MOC3/06
Metalaxyl dont Metalaxyl-M	ND	0,01	MOC3/06
Metazachlor	ND	0,01	MOC3/06
Methidathion	ND	0,01	MOC3/06
Methiocarbe	ND	0,01	MOC3/06
Methoxychlore	ND	0,01	MOC3/06
Metolachlore dont S-Metolachlore	ND	0,01	MOC3/06
Metribuzine	ND	0,01	MOC3/06
Monalide	ND	0,01	MOC3/06
Myclobutanil	ND	0,01	MOC3/06
Napropamide	ND	0,01	MOC3/06
Oxadiazon	ND	0,01	MOC3/06
Oxadixyl	ND	0,01	MOC3/06
Oxyfluorfene	ND	0,01	MOC3/06
Parathion-ethyl	ND	0,01	MOC3/06
Parathion-methyl	ND	0,01	MOC3/06
Penconazole	ND	0,01	MOC3/06
Pendimethaline	ND	0,01	MOC3/06
Permethrine(cis + trans)	ND	0,01	MOC3/06
Phosalone	ND	0,01	MOC3/06
Piperonyl butoxide	4,5	0,01	MOC3/06
Pirimicarb	ND	0,01	MOC3/06
Pirimiphos-ethyl	ND	0,01	MOC3/06
Pirimiphos-methyl	0,030	0,01	MOC3/06
Prochloraz(+TCP)	ND	0,01	MOC3/06
Procymidone	ND	0,01	MOC3/06
Profenophos	ND	0,01	MOC3/06
Propiconazole	ND	0,01	MOC3/06
Propyzamide	ND	0,01	MOC3/06
Proquinazid	ND	0,01	MOC3/06
Prosulfocarbe	ND	0,01	MOC3/06
Pyridaben	ND	0,01	MOC3/06
Pyridalyl	ND	0,01	MOC3/06
Pyridaphenthion	ND	0,01	MOC3/06
Pyrimethanil	ND	0,01	MOC3/06
Pyriproxyfen	ND	0,01	MOC3/06
Quinoxyfen	ND	0,01	MOC3/06
Quintozene(+PCA)	ND	0,01	MOC3/06
Quizalofop-ethyl	ND	0,01	MOC3/06
S 421	ND	0,01	MOC3/06
Sebuthylazine	ND	0,01	MOC3/06
Tebuconazole	0,11	0,01	MOC3/06
Tebufenpyrad	ND	0,01	MOC3/06
Tebupirimphos	ND	0,01	MOC3/06
Tefluthrine	ND	0,01	MOC3/06
Terbufos	ND	0,01	MOC3/06
Terbuthylazine	ND	0,01	MOC3/06
Tetramethrine	ND	0,01	MOC3/06
Tolclofos-methyl	ND	0,01	MOC3/06
Tolylfluanid	ND	0,01	MOC3/06
Triadimefone+Triadimenol	ND	0,01	MOC3/06
Triazophos	ND	0,01	MOC3/06
Trifluraline	ND	0,01	MOC3/06
Valifenalate	ND	0,01	MOC3/06
Vinclozoline(+3,5-dichloroaniline)	ND	0,01	MOC3/06
Zoxamide	ND	0,01	MOC3/06

Métaux lourds et ETM

	Résultat	LQ	méthode
Unité ⇩ : mg/kg			
Plomb	< 0,04	0,04	MOC3/92
Cadmium	< 0,01	0,01	MOC3/92
Arsenic	< 0,03	0,03	MOC3/92
Mercure	< 0,005	0,005	MOC3/92
Antimoine	< 0,02	0,02	MOC3/92

Mycotoxines

	Résultat	LQ	méthode
Unité ⇩ : µg/kg			
Aflatoxine B1	ND	2	MOC3111
Aflatoxines (Σ B1,B2, G1,G2)	ND	8	MOC3111
Ochratoxine A	ND	2	MOC3111
Zearalenone	ND	10	MOC3111
Deoxynivalenol	ND	50	MOC3111

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Statement Heavy metals quantification with validated method CERAMOSIDES™ OIL NEUTRA

Heavy metals are quantified in an external laboratory using an internal method based on NF EN 15763 method, by ICP-MS.

We hereby certify that this internal method used had been validated on the matrix CERAMOSIDES™ OIL NEUTRA.

Fait à VILLERS SUR FERE,
Le 20/05/2020

Valérie BIZOT
Quality Manager

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SARL au capital de 45 000 € RCS SOISSONS B 414 332 817 SIRET : 414 332 817 00025 – APE : 1041 A – N° TVA FR 144 14 332 817

Phytocontrol AGRIFOOD

EPI FRANCE
VALERIE BIZOT
3 RUE DE PREAUX
02130 VILLERS SUR FERE

- This report cancels and replaces the previous version. We thank you for destroying the previous version of this report.

Laboratory reference	19/PN114316		
Customer reference	CERAMOSIDES POWDER NEUTRA Lot: 21190328		
Type of sample	CERAMOSIDES POWDER NEUTRA	**Weight**	107g
Status	Grind	**Temperature at reception**	Room
Date of reception	22/07/2019 11:20:41	**Expiration date**	22/08/2019
Packaging	Customer	**Transport**	La Poste
Quotation reference	DPA180754	**Regional agency**	Phytocontrol Lille

Ordered analysis

Pesticides	Dithiocarbamates (CS2) Glyphosate and AMPA Multirésidus GC250 + Multirésidus LC350
Heavy metals	Lead Cadmium Arsenic Mercury Antimony
Mycotoxines	Aflatoxins B1 B2 G1 G2 + Ochratoxin A + Deoxynivalenol (DON) + Zearalenone
Polycyclic aromatic hydrocarbons (PaH)	4 PAHs
Other contaminants	Bromides

Sample at reception

Results of analysis

	Result	Unit	LOQ	Limit		End of analysis
Pesticides						
Multiresidues GC 250						
Piperonyl butoxide	0,25 ± 0,10	mg/kg	0,01		(1)	26/07/2019
Pirimiphos-methyl	D < 0,01	mg/kg	0,01			26/07/2019
Multiresidues LC 350	ND					25/07/2019
Specific monoresidues						
AMPA	ND	mg/kg	0,01			24/07/2019
Dithiocarbamates (CS2)	ND	mg/kg	0,01			24/07/2019
Glyphosate	ND	mg/kg	0,01			24/07/2019
Heavy metals						
Lead	0,045 ± 0,013	mg/kg	0,04			23/07/2019
Cadmium	< 0,01	mg/kg	0,01			23/07/2019
Arsenic	< 0,03	mg/kg	0,03			23/07/2019
Mercury	< 0,005	mg/kg	0,005			23/07/2019
Antimony	< 0,02	mg/kg	0,02			23/07/2019
Mycotoxines						
Aflatoxin B1	ND	µg/kg	1			24/07/2019
Aflatoxin B2	ND	µg/kg	1			24/07/2019
Aflatoxin G1	ND	µg/kg	1			24/07/2019
Aflatoxin G2	ND	µg/kg	1			24/07/2019
Aflatoxins (Σ B1,B2, G1,G2)	ND	µg/kg	1			24/07/2019
Ochratoxin A	ND	µg/kg	1			24/07/2019
Zearalenon	ND	µg/kg	10			24/07/2019
Deoxynivalenol	ND	µg/kg	50			24/07/2019
Polycyclic aromatic hydrocarbons (PaH)						
Benzo(a)pyrene	ND	µg/kg	0,5			24/07/2019
Benzo(a)anthracene	ND	µg/kg	0,5			24/07/2019
Benzo(b)fluoranthene	ND	µg/kg	0,5			24/07/2019
Chrysene	ND	µg/kg	0,5			24/07/2019
Sum of the 4 HAP	ND	µg/kg	0,5			24/07/2019
Other contaminants						
Bromides	ND	mg/kg	5			23/07/2019

Detail of the analyzed parameters and the methods used in following page(s)

Legend

ND = Not Detected D = Detected LOQ = Limit of Quantification NA = Not Analysed

(m):assayed without associated analyte(s) with analyzes carried out only within the scope of Regulation No 396/2005 and its amendments or Directives 2006/125 / EC and 2006/141 / EC.

Used methods mentioned in following page(s) :

MOC3/05 version 0 : Determination of pesticide residue content by GC-MS-MS : internal method.

MOC3/11 version 0 : Determination of the content in dithiocarbamates on fruits and vegetables by GC-MS/HS : internal method.

MOC3/17 version 0 : Determination of the content in glyphosate/AMPA and/or glufosinate on vegetables by LC-MS-MS : internal method.

MOC3/18 version 0 : Determination of the content in nitrates and nitrites by IC : internal method.

MOC3/23 version 2 : Determination of the content of PAH by GC-MS/MS : internal method.

MOC3/92 version 13 : Determination of heavy elements (metallic and non-metallic) content on product of animal and vegetable origin by ICP-MS: internal method.

MOC3111 version 2 : Determination of mycotoxins in product of plant origin LC-MS-MS: internal method.

MOC3407 version 2 : Determination of pesticide residue content by LC-MS-MS : internal method.

Comments

The analytical results are only valid within the perimeter of application of the used method.

The limit values are based on the regulations and / or guidelines and / or recommendations listed below :

Pesticides

• Human and Animal Nutrition (raw materials): Regulation (EC) No 396/2005 and subsequent amendments on maximum residue levels of pesticides in or on food and feed

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of plant and animal origin.
• Animal Feed: Directive 2002/32 and subsequent amendments on undesirable substances in animal feed. The maximum levels apply to feedingstuffs with a moisture content of 12%.

Heavy metals

• Food:
Regulation (EC) No 1881/2006 and subsequent amendments setting maximum levels for certain contaminants in foodstuffs.
Copper and Mercury (depending on matrix) : Regulation (EC) No 396/2005 and subsequent amendments on maximum residue levels of pesticides in or on food and feed of plant and animal origin.
• For wine: OIV - Maximum acceptable limits of various elements in wine (2015 edition).
• Animal Feed: Directive 2002/32 and subsequent amendments on undesirable substances in animal feed. The maximum levels apply to feedingstuffs with a moisture content of 12%.
• Food additives: Regulation (EU) n°231/2012 and subsequent amendments laying down specifications for food additives listed in Annexes II and III to Regulation (EC) N°1333/2008 of the European Parliament and of the council.

Mycotoxines

• Food : Regulation (EC) No 1881/2006 and subsequent amendments setting maximum levels for certain contaminants in foodstuffs.
Recommendations 2013/165/UE on the presence of T-2 toxin and HT-2 in cereals and cereal products.
• Animal Feed: Directive 2002/32 and subsequent amendments on undesirable substances in animal feed. The maximum levels apply to feedingstuffs with a moisture content of 12%.

Polycyclic aromatic hydrocarbons (PaH)

• Food: Regulation (EC) No 1881/2006 and subsequent amendments setting maximum levels for certain contaminants in foodstuffs.
Units may vary depending on the matrix: µg/kg (raw) or µg/kg MG (fat).

According to the laboratory recommendations defined in the general conditions of sale, the quantity or number of sample units received is not sufficient. The analyses are continued without affecting the validity of the results, however the representativeness of the sampling may not follow the requirements defined in the regulations in force.

(1) Le pipéronyl butoxide (PBO) est considéré comme un synergisant des pyrèthres naturels au niveau Européen, de ce fait aucune LMR communautaire n'est définie.
En revanche, pour les céréales cultivées en France, les autorités compétentes ont fixé une LMR nationale à 10mg/kg. Cette LMR ne s'applique pas aux céréales importées.
Dans le cadre de l'agriculture biologique, le CNAB (Comité National de l'Agriculture Biologique) a décidé dans sa réunion du 8 Décembre 2015, d'interdire toutes solutions phytosanitaires AB contenant du pipéronyl butoxyde sur le territoire français avec un délai de fin d'utilisation des stocks fixé au 30 Septembre 2017. En cas de détection en PBO, il convient de vous rapprocher de votre organisme certificateur.

Signature

The updating of regulatory information as regard to the European regulation or any other published standard is ensured by our Regulatory Monitoring department.

Report validated by :

Audrey COSTE
Analytical Validation

- This certificate was electrically produced and validated. The name and the function of the persons in charge on it document were produced on a protected procedure and personalised. This certificate is authentic. A paper version signed of this document can be obtained on simple demand.
- The results of analysis concern only objects subjected to the analysis.
- In absence of accurate and of opposite indication, the Limit of Detection is equal to half of the Limit of Quantification (excluding subcontracted parameters).
- The reproduction of this report is authorized only in its complete form except when authorised by the laboratory.
- Uncertainty communicated on demand.
- PHYTOCONTROL is accredited by the FAVV-AFSCA and is approved by INAO, BNN and by QS, and certified ISO 14001 by Afnor.
- This report cancels and replaces the previous report.

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Pesticides

Multiresidues GC 250

FB3/02.c vers. 25 (02/05/2019)

Unit ◊ : mg/kg	Result	LOQ	method
1,4-Dimethylnaphtalene	ND	0,01	MOC3/05
2,4,6 trichlorophenol (TCP) (r	ND	0,01	MOC3/05
2-Phenylphenol(somme)	ND		
2-Methoxybiphenyl	ND	0,01	MOC3/05
2-Phenylhydroquinone	ND	0,01	MOC3/05
2-Phenylphenol	ND	0,01	MOC3/05
3,4-dichloroaniline	ND	0,01	MOC3/05
4,4-Dichlorobenzophenone	ND	0,01	MOC3/05
Acetochlore	ND	0,01	MOC3/05
Acibenzolar-S-methyl (m)	ND	0,01	MOC3/05
Aclonifen	ND	0,01	MOC3/05
Acrinathrine	ND	0,01	MOC3/05
Alachlore	ND	0,01	MOC3/05
Ametryn	ND	0,01	MOC3/05
Amisulbrom	ND	0,01	MOC3/05
Atrazine	ND	0,01	MOC3/05
Benalaxyl dont Benalaxyl-M	ND	0,01	MOC3/05
Bendiocarb	ND	0,01	MOC3/05
Benfluraline	ND	0,01	MOC3/05
Benoxacor	ND	0,01	MOC3/05
Bifenox	ND	0,01	MOC3/05
Bifenthrine	ND	0,01	MOC3/05
Biphenyl	ND	0,01	MOC3/05
Bitertanol	ND	0,01	MOC3/05
Bromocyclen	ND	0,01	MOC3/05
Bromophos-ethyl	ND	0,01	MOC3/05
Bromophos-methyl	ND	0,01	MOC3/05
Bromopropylate	ND	0,01	MOC3/05
Butachlor	ND	0,01	MOC3/05
Butraline	ND	0,01	MOC3/05
Captafol	ND	0,01	MOC3/05
Captan(somme)	ND		
Captan	ND	0,01	MOC3/05
Tetrahydrophtalimide (THF	ND	0,01	MOC3/05
Carbaryl	ND	0,01	MOC3/05
Carbofuran(+3-hydroxy) (m)	ND		
Carbofuran	ND	0,01	MOC3/05
Carbofuran-3-Hydroxy	ND	0,01	MOC3/05
Furathiocarbe	ND	0,01	MOC3/05
Carbophenothion	ND	0,01	MOC3/05
Carfentrazone-ethyl	ND	0,01	MOC3/05
Chlorbenside	ND	0,01	MOC3/05
Chlordane(cis+trans)	ND	0,01	MOC3/05
Chlorfenapyr	ND	0,01	MOC3/05
Chlorfenson	ND	0,01	MOC3/05
Chlorfenvinphos	ND	0,01	MOC3/05
Chlorobenzilate	ND	0,01	MOC3/05
Chlorothalonil	ND	0,01	MOC3/05
Chlorpropham	ND	0,01	MOC3/05
Chlorpyrifos	ND	0,01	MOC3/05
Chlorpyrifos-methyl	ND	0,01	MOC3/05
Chlorthal dimethyl	ND	0,01	MOC3/05
Chlorthiophos	ND	0,01	MOC3/05
Chlozolinate	ND	0,01	MOC3/05
Clomazone	ND	0,01	MOC3/05
Coumaphos	ND	0,01	MOC3/05
Cyfluthrine (β+γ)	ND	0,01	MOC3/05
Cyhalofop-butyl	ND	0,01	MOC3/05
Cyhalothrine(∑ des isomères	ND	0,01	MOC3/05
Cymiazole	ND	0,01	MOC3/05
Cypermethrine(α+β+θ+ζ)	ND	0,01	MOC3/05
Cyproconazole	ND	0,01	MOC3/05
Cyprodinil	ND	0,01	MOC3/05
DDT(∑ des isomères)	ND		
o,p'-DDT	ND	0,01	MOC3/05
p,p'-DDT	ND	0,01	MOC3/05
p,p'-DDE	ND	0,01	MOC3/05
p,p'-TDE(DDD)	ND	0,01	MOC3/05
Deltamethrine	ND	0,01	MOC3/05
Demeton-S-methyl	ND	0,01	MOC3/05
Dialifos	ND	0,01	MOC3/05
Dichlobenil	ND	0,01	MOC3/05
Dichlofenthion	ND	0,01	MOC3/05
Dichlofluanide	ND	0,01	MOC3/05
Dichlorvos	ND	0,01	MOC3/05
Diclofop-methyl (m)	ND	0,01	MOC3/05
Dicofol(∑ des isomères)	ND		
Dicrotophos	ND	0,01	MOC3/05
Dieldrin(+Aldrin)	ND		
Aldrin	ND	0,01	MOC3/05
Dieldrin	ND	0,01	MOC3/05
Diethofencarb	ND	0,01	MOC3/05
Difenoconazole	ND	0,01	MOC3/05
Diflufenican	ND	0,01	MOC3/05
Dimetachlor	ND	0,01	MOC3/05
Dinitramine	ND	0,01	MOC3/05
Diphenylamine	ND	0,01	MOC3/05
Disulfoton (m)	ND	0,01	MOC3/05
Ditalimfos	ND	0,01	MOC3/05
Edifenphos	ND	0,01	MOC3/05
Endosulfan (α+β+sulfate)	ND		
Endosulfan α	ND	0,01	MOC3/05
Endosulfan β	ND	0,01	MOC3/05
Endosulfan sulfate	ND	0,01	MOC3/05
Endrin	ND	0,01	MOC3/05
Endrin-ketone	ND	0,01	MOC3/05
EPN	ND	0,01	MOC3/05
Ethalfluraline	ND	0,01	MOC3/05
Ethiofencarb	ND	0,01	MOC3/05
Ethion	ND	0,01	MOC3/05
Ethofumesate (m)	ND	0,01	MOC3/05
Ethoprophos	ND	0,01	MOC3/05
Ethoxyquine	ND	0,01	MOC3/05
Etofenprox	ND	0,01	MOC3/05
Etridiazole	ND	0,01	MOC3/05
Etrimfos	ND	0,01	MOC3/05
Famoxadone	ND	0,01	MOC3/05
Famphur	ND	0,01	MOC3/05
Fenamiphos (m)	ND	0,01	MOC3/05
Fenarimol	ND	0,01	MOC3/05
Fenazaquin	ND	0,01	MOC3/05
Fenchlorphos (m)	ND	0,01	MOC3/05
Fenhexamide	ND	0,01	MOC3/05
Fenitrothion	ND	0,01	MOC3/05
Fenobucarbe	ND	0,01	MOC3/05
Fenpropathrine	ND	0,01	MOC3/05
Fenpropimorphe	ND	0,01	MOC3/05
Fenvalerate (∑ des isomères	ND	0,01	MOC3/05
Fipronil(+sulfone)	ND		
Fipronil	ND	0,005	MOC3/05
Fipronil-sulfone	ND	0,005	MOC3/05
Fipronil-desulfinyl	ND	0,01	MOC3/05
Fluazifop-p-butyl (m)	ND	0,01	MOC3/05
Fluchloralin	ND	0,01	MOC3/05
Flucythrinate	ND	0,01	MOC3/05
Fludioxonil	ND	0,01	MOC3/05
Flufenacet (m)	ND	0,01	MOC3/05
Fluopicolide	ND	0,01	MOC3/05
Flurochloridone	ND	0,01	MOC3/05
Fluroxypyr-methylheptyl ester (m)	ND	0,01	MOC3/05
Flusilazole	ND	0,01	MOC3/05
Flutolanil	ND	0,01	MOC3/05
Flutriafol	ND	0,01	MOC3/05
Fluvalinate (Tau)	ND	0,01	MOC3/05
Folpet(somme)	ND		
Folpet	ND	0,01	MOC3/05
Phtalimide	ND	0,01	MOC3/05
Fonofos	ND	0,01	MOC3/05
Formothion	ND	0,01	MOC3/05
Furalaxyl	ND	0,01	MOC3/05
Haloxyfop-2-ethoxyethyl (m)	ND	0,01	MOC3/05
Haloxyfop-methyl(R+S) (m)	ND	0,01	MOC3/05
HCB	ND	0,01	MOC3/05
HCH alpha	ND	0,01	MOC3/05
HCH beta	ND	0,01	MOC3/05
HCH gamma	ND	0,01	MOC3/05
Heptachlore(+epoxyde)	ND		
Heptachlore	ND	0,01	MOC3/05
Heptachlore epoxyde cis-	ND	0,01	MOC3/05
Heptachlore epoxyde trans	ND	0,01	MOC3/05
Heptenophos	ND	0,01	MOC3/05
Hexazinone	ND	0,01	MOC3/05
Iodofenphos	ND	0,01	MOC3/05
Iprodione	ND	0,01	MOC3/05
Isobenzan	ND	0,01	MOC3/05
Isodrine	ND	0,01	MOC3/05
Isofenphos-ethyl	ND	0,01	MOC3/05
Isofenphos-methyl	ND	0,01	MOC3/05
Isoxadifen-ethyl	ND	0,01	MOC3/05
Leptophos	ND	0,01	MOC3/05
Malathion(+Malaoxon)	ND		
Malathion	ND	0,01	MOC3/05
Malaoxon	ND	0,01	MOC3/05
Mepanipyrim	ND	0,01	MOC3/05
Mepronil	ND	0,01	MOC3/05
Metalaxyl dont Metalaxyl-M	ND	0,01	MOC3/05
Metazachlor	ND	0,01	MOC3/05
Methacrifos	ND	0,01	MOC3/05
Methidathion	ND	0,01	MOC3/05
Methoxychlore	ND	0,01	MOC3/05
Metolachlore dont S-Metolachlore	ND	0,01	MOC3/05
Mirex	ND	0,01	MOC3/05
Myclobutanil	ND	0,01	MOC3/05
Nitrofene	ND	0,01	MOC3/05
Nitrothal isopropyle	ND	0,01	MOC3/05
Oxadiazon	ND	0,01	MOC3/05

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Oxadixyl	ND	0,01	MOC3/05	
Oxyfluorfene	ND	0,01	MOC3/05	
Parathion-ethyl	ND	0,01	MOC3/05	
Parathion-methyl (m)	ND	0,01	MOC3/05	
PCB 028	ND	0,01	MOC3/05	
PCB 052	ND	0,01	MOC3/05	
PCB 101	ND	0,01	MOC3/05	
PCB 118	ND	0,01	MOC3/05	
PCB 138	ND	0,01	MOC3/05	
PCB 153	ND	0,01	MOC3/05	
PCB 180	ND	0,01	MOC3/05	
Penconazole	ND	0,01	MOC3/05	
Pendimethaline	ND	0,01	MOC3/05	
Pentachloroanisole	ND	0,01	MOC3/05	
Permethrine(cis + trans)	ND	0,01	MOC3/05	
Perthane	ND	0,01	MOC3/05	
Phenothrine	ND	0,01	MOC3/05	
Phenthoate	ND	0,01	MOC3/05	
Phosalone	ND	0,01	MOC3/05	
Piperonyl butoxide	0,25	0,01	MOC3/05	
Pirimicarb	ND	0,01	MOC3/05	
Pirimiphos-ethyl	ND	0,01	MOC3/05	
Pirimiphos-methyl	D < 0,01	0,01	MOC3/05	
Plifenate	ND	0,01	MOC3/05	
Pretilachlore	ND	0,01	MOC3/05	
Procymidone	ND	0,01	MOC3/05	
Profenophos	ND	0,01	MOC3/05	
Prometryn	ND	0,01	MOC3/05	
Propachlore (m)	ND	0,01	MOC3/05	
Propazine	ND	0,01	MOC3/05	
Propetamphos	ND	0,01	MOC3/05	
Prophame	ND	0,01	MOC3/05	
Propiconazole	ND	0,01	MOC3/05	
Propyzamide	ND	0,01	MOC3/05	
Proquinazid	ND	0,01	MOC3/05	
Prosulfocarbe	ND	0,01	MOC3/05	
Prothiophos	ND	0,01	MOC3/05	
Prothoate	ND	0,01	MOC3/05	
Pyrazophos	ND	0,01	MOC3/05	
Pyridaben	ND	0,01	MOC3/05	
Pyridalyl	ND	0,01	MOC3/05	
Pyridaphenthion	ND	0,01	MOC3/05	
Pyrifenox	ND	0,01	MOC3/05	
Pyrimethanil	ND	0,01	MOC3/05	
Pyriproxyfen	ND	0,01	MOC3/05	
Quinalphos	ND	0,01	MOC3/05	
Quinomethionate	ND	0,01	MOC3/05	
Quinoxyfen	ND	0,01	MOC3/05	
Quintozene(+PCA)	ND			
Quintozene	ND	0,01	MOC3/05	
Pentachloroaniline (PCA)	ND	0,01	MOC3/05	
Quizalofop-ethyl	ND	0,01	MOC3/05	
S 421	ND	0,01	MOC3/05	
Sebuthylazine	ND	0,01	MOC3/05	
Secbumeton	ND	0,01	MOC3/05	
Sulfotep	ND	0,01	MOC3/05	
Sulprofos	ND	0,01	MOC3/05	
Tebuconazole	ND	0,01	MOC3/05	
Tebufenpyrad	ND	0,01	MOC3/05	
Tebupirimphos	ND	0,01	MOC3/05	
Tecnazene	ND	0,01	MOC3/05	
Tefluthrine	ND	0,01	MOC3/05	
Terbacil	ND	0,01	MOC3/05	
Terbufos	ND	0,01	MOC3/05	
Terbuthylazine	ND	0,01	MOC3/05	
Terbutryne	ND	0,01	MOC3/05	
Tetrachlorvinphos	ND	0,01	MOC3/05	
Tetradifon	ND	0,01	MOC3/05	
Tetramethrine	ND	0,01	MOC3/05	
Tetrasul	ND	0,01	MOC3/05	
Tolclofos-methyl	ND	0,01	MOC3/05	
Tolylfluanid (m)	ND	0,01	MOC3/05	
Tralomethrine	ND	0,01	MOC3/05	
Transfluthrine	ND	0,01	MOC3/05	
Triadimefon	ND	0,01	MOC3/05	
Triadimenol	ND	0,01	MOC3/05	
Triallate	ND	0,01	MOC3/05	
Triamiphos	ND	0,01	MOC3/05	
Triazophos	ND	0,01	MOC3/05	
Trichloronat	ND	0,01	MOC3/05	
Trifluraline	ND	0,01	MOC3/05	
Valifenalate	ND	0,01	MOC3/05	
Vinclozoline	ND	0,01	MOC3/05	
Zoxamide	ND	0,01	MOC3/05	

Multiresidues LC 350

FB3/02.A vers. 5 (02/05/2019)

	Result	LOQ	method
Unit ⊕ : mg/kg			
2,4 D(acide libre) (m)	ND	0,01	MOC3407
6-Benzyladenine	ND	0,01	MOC3407
Abamectine(somme)	ND		
Avermectine B1a	ND	0,01	MOC3407
Avermectine B1b	ND	0,01	MOC3407
8,9-Z-AvermectinB1a	ND	0,01	MOC3407
Acephate	ND	0,01	MOC3407
Acequinocyl	ND	0,01	MOC3407
Acetamipride	ND	0,01	MOC3407
Aldicarb(somme)	ND		
Aldicarb	ND	0,01	MOC3407
Aldicarb sulfone	ND	0,01	MOC3407
Aldicarb sulfoxide	ND	0,01	MOC3407
Ametoctradine	ND	0,01	MOC3407
Amidosulfuron	ND	0,01	MOC3407
Amitraze(somme)	ND		
Amitraze	ND	0,01	MOC3407
2,4-Dimethylaniline	ND	0,01	MOC3407
N-(2,4-Dimethylphenyl)formamide	ND	0,01	MOC3407
N-2,4-Dimethylphenyl-Np-methylformamidine HCl	ND	0,01	MOC3407
Amitrole	ND	0,01	MOC3407
Asulam	ND	0,01	MOC3407
Atrazine desisopropyl	ND	0,01	MOC3407
Atrazine-desethyl(+deisoprop	ND	0,01	MOC3407
Azaconazole	ND	0,01	MOC3407
Azadirachtin(somme)	ND		
Azadirachtin A	ND	0,01	MOC3407
Azadirachtin B	ND	0,01	MOC3407
Azamethiphos	ND	0,01	MOC3407
Azimsulfuron	ND	0,01	MOC3407
Azinphos-ethyl	ND	0,01	MOC3407
Azinphos-methyl	ND	0,01	MOC3407
Azoxystrobine	ND	0,01	MOC3407
Beflubutamide	ND	0,01	MOC3407
Bensulfuron-methyl	ND	0,01	MOC3407
Bentazone(somme) (m)	ND		
Bentazone	ND	0,01	MOC3407
Bentazone 8 hydroxy	ND	0,01	MOC3407
Bentazone 6 hydroxy	ND	0,01	MOC3407
Benthiavalicarb-isopropyl (m)	ND	0,01	MOC3407
Benzovindiflupyr	ND	0,01	MOC3407
Bifenazate(+diazene)	ND		
Bifenazate	ND	0,01	MOC3407
Bifenazate-diazene	ND	0,01	MOC3407
Bispyribac-sodium	ND	0,01	MOC3407
Bixafen	ND	0,01	MOC3407
Boscalide	ND	0,01	MOC3407
Bromacil	ND	0,01	MOC3407
Bromoxynil	ND	0,01	MOC3407
Bromuconazole	ND	0,01	MOC3407
Bupirimate	ND	0,01	MOC3407
Buprofezin	ND	0,01	MOC3407
Butoxycarboxim	ND	0,01	MOC3407
Butoxycarboxim-sulfoxide	ND	0,01	MOC3407
Buturon	ND	0,01	MOC3407
Cadusafos	ND	0,01	MOC3407
Carbendazime(+Benomyl)	ND	0,01	MOC3407
Carbétamide (∑ de la carbétamide et de son isomère)	ND	0,01	MOC3407
Carbofuran(somme LC) (m)	ND		
Benfuracarbe	ND	0,01	MOC3407
Carbosulfan	ND	0,01	MOC3407
Carboxine	ND	0,01	MOC3407
Chlorantraniliprole	ND	0,01	MOC3407
Chlorfluazuron	ND	0,01	MOC3407
Chloridazon(somme)	ND		
Chloridazon	ND	0,01	MOC3407
Chloridazon-desphenyl	ND	0,01	MOC3407
Chloridazon-methyl-desphen	ND	0,01	MOC3407
Chlorotoluron	ND	0,01	MOC3407
Chloroxuron	ND	0,01	MOC3407
Chlorpyrifos-methyl-desméth (m)	ND	0,02	MOC3407
Chlorsulfuron	ND	0,01	MOC3407
Chromafenozide	ND	0,01	MOC3407
Cinidon-ethyl	ND	0,01	MOC3407
Cinmethylin	ND	0,01	MOC3407
Cinosulfuron	ND	0,01	MOC3407
Clethodim(somme) (m)	ND		
Clethodim	ND	0,01	MOC3407
Clethodim sulfoxide	ND	0,01	MOC3407
Sethoxydim	ND	0,01	MOC3407
Clodinafop-propargyl	ND	0,01	MOC3407
Clofentezine	ND	0,01	MOC3407
Clothianidine	ND	0,01	MOC3407
Cyanazine	ND	0,01	MOC3407
Cyantraniliprole	ND	0,01	MOC3407
Cyazofamide	ND	0,01	MOC3407
Cycloxydime (m)	ND	0,01	MOC3407
Cycluron	ND	0,01	MOC3407
Cyflufenamid	ND	0,01	MOC3407
Cymoxanil	ND	0,01	MOC3407
Cyprosulfamide	ND	0,01	MOC3407
Cyromazine	ND	0,01	MOC3407

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S.A.S. au Capital de 1.000.000 euros - SIRET 490 024 049 00028 RCS Nîmes - TVA intracom FR08490024049 - APE 7120B

Daminozide (m)	ND	0,01	MOC3407
Dazomet (m)	ND	0,01	MOC3407
Demeton-S	ND	0,01	MOC3407
Oxydemeton-methyl(somme)	ND		
Demeton-S-methyl sulfone	ND	0,01	MOC3407
Oxydemeton-methyl	ND	0,01	MOC3407
Desmediphame	ND	0,01	MOC3407
Desmetryn	ND	0,01	MOC3407
Diafenthiuron	ND	0,01	MOC3407
Diallate	ND	0,01	MOC3407
Diazinon	ND	0,01	MOC3407
Dichlorprop(acide libre) (m)	ND	0,01	MOC3407
Diclobutrazol	ND	0,01	MOC3407
Dicloran	ND	0,01	MOC3407
Difenacoum	ND	0,01	MOC3407
Difenamide	ND	0,01	MOC3407
Difethialone	ND	0,01	MOC3407
Diflubenzuron	ND	0,01	MOC3407
Dimethenamid-P(Σ des isomeres)	ND	0,01	MOC3407
Dimethoate	ND	0,01	MOC3407
Dimethomorphe(Σ des isomeres)	ND	0,01	MOC3407
Dimoxystrobine	ND	0,01	MOC3407
Diniconazole(Σ des isomères	ND	0,01	MOC3407
Dinocap(somme)	ND		
Dinocap(Σ des isomères) (	ND	0,01	MOC3407
Meptyldinocap-phenol (2,4 DNOP) (m)	ND	0,01	MOC3407
Dinoseb (m)	ND	0,01	MOC3407
Dinotefuran	ND	0,01	MOC3407
Dinoterb	ND	0,01	MOC3407
Disulfoton-sulfoxe(+sulfoxide (m)	ND		
Disulfoton-sulfone	ND	0,01	MOC3407
Disulfoton-sulfoxide	ND	0,01	MOC3407
Dithianon	ND	0,01	MOC3407
Diuron	ND	0,01	MOC3407
DMST (m)	ND	0,01	MOC3407
DNOC	ND	0,01	MOC3407
Dodemorphe	ND	0,01	MOC3407
Dodine	ND	0,01	MOC3407
Emamectine-benzoate B1a	ND	0,01	MOC3407
Emamectine-benzoate B1b	ND	0,01	MOC3407
Epoxiconazole	ND	0,01	MOC3407
EPTC	ND	0,01	MOC3407
Ethametsulfuron methyl	ND	0,01	MOC3407
Ethidimuron	ND	0,01	MOC3407
Ethiofencarb sulfone	ND	0,01	MOC3407
Ethiofencarb sulfoxide	ND	0,01	MOC3407
Ethiprole	ND	0,01	MOC3407
Ethirimol	ND	0,01	MOC3407
Ethoxysulfuron	ND	0,01	MOC3407
Etoxazole	ND	0,01	MOC3407
Fenamidone	ND	0,01	MOC3407
Fenamiphos-sulfone(+sulfoxide) (m)	ND		
Fenamiphos-sulfone	ND	0,01	MOC3407
Fenamiphos-sulfoxide	ND	0,01	MOC3407
Fenbuconazole	ND	0,01	MOC3407
Fenchlorphos oxon (m)	ND	0,01	MOC3407
Fenoxaprop-ethyl	ND	0,01	MOC3407
Fenoxycarbe	ND	0,01	MOC3407
Fenpropidine	ND	0,01	MOC3407
Fenpyrazamine	ND	0,01	MOC3407
Fenpyroximate	ND	0,01	MOC3407
Fensulfothion	ND	0,01	MOC3407
Fensulfothion-oxon	ND	0,01	MOC3407
Fensulfothion-oxon-sulfone	ND	0,01	MOC3407
Fensulfothion-sulfone	ND	0,01	MOC3407
Fenthion(somme)	ND		
Fenthion	ND	0,01	MOC3407
Fenthion-sulfone	ND	0,01	MOC3407
Fenthion-sulfoxide	ND	0,01	MOC3407
Fenthion-oxon	ND	0,01	MOC3407
Fenthion-oxon-sulfone	ND	0,01	MOC3407
Fenthion-oxon-sulfoxide	ND	0,01	MOC3407
Fenuron	ND	0,01	MOC3407
Flazasulfuron	ND	0,01	MOC3407
Flonicamide(+TNFA+TNFG)	ND		
Flonicamide	ND	0,01	MOC3407
TFNA	ND	0,01	MOC3407
TFNG	ND	0,01	MOC3407
Florasulam	ND	0,01	MOC3407
Fluazifop(free acid) (m)	ND	0,01	MOC3407
Fluazinam	ND	0,01	MOC3407
Flufenacet(somme) (m)	ND		
Flufenacet ESA	ND	0,01	MOC3407
Flufenacet FOE 5043	ND	0,01	MOC3407
Flufenacet OA	ND	0,01	MOC3407
Flufenoxuron	ND	0,01	MOC3407
Flufenzine	ND	0,01	MOC3407
Flumetralin	ND	0,01	MOC3407
Fluometuron	ND	0,01	MOC3407
Fluopyram	ND	0,01	MOC3407
Fluoxastrobine	ND	0,01	MOC3407
Flupyradifurone	ND	0,01	MOC3407
Flupyrsulfuron methyl	ND	0,01	MOC3407
Fluquinconazole	ND	0,01	MOC3407
Fluroxypyr(acide libre) (m)	ND	0,01	MOC3407
Flurprimidol	ND	0,01	MOC3407
Flurtamone	ND	0,01	MOC3407
Fluxapyroxad	ND	0,01	MOC3407
Fomesafen	ND	0,01	MOC3407
Foramsulfuron	ND	0,01	MOC3407
Forchlorfenuron	ND	0,01	MOC3407
Formetanate (hydrochloride)	ND	0,01	MOC3407
Fosthiazate	ND	0,01	MOC3407
Fuberidazole	ND	0,01	MOC3407
Furametpyr	ND	0,01	MOC3407
Furmecyclox	ND	0,01	MOC3407
Halauxifen-methyl	ND	0,01	MOC3407
Halfenprox	ND	0,01	MOC3407
Halosulfuron-methyl	ND	0,01	MOC3407
Haloxyfop(acide libre) (m)	ND	0,01	MOC3407
Hexaconazole	ND	0,01	MOC3407
Hexaflumuron	ND	0,01	MOC3407
Hexythiazox	ND	0,01	MOC3407
Hydramethylnon	ND	0,01	MOC3407
Imazalil	ND	0,01	MOC3407
Imazamox	ND	0,01	MOC3407
Imazaquin	ND	0,01	MOC3407
Imazosulfuron	ND	0,01	MOC3407
Imibenconazole	ND	0,01	MOC3407
Imidachlopride	ND	0,01	MOC3407
Indoxacarb (Σénantiomères)	ND	0,01	MOC3407
Iodosulfuron-methyl	ND	0,01	MOC3407
Ioxynil (m)	ND	0,01	MOC3407
Ipconazole	ND	0,01	MOC3407
Iprobenfos	ND	0,01	MOC3407
Iprovalicarbe	ND	0,01	MOC3407
Isazofos	ND	0,01	MOC3407
Isocarbophos	ND	0,01	MOC3407
Isofetamid	ND	0,01	MOC3407
Isoprocarb	ND	0,01	MOC3407
Isopropaline	ND	0,01	MOC3407
Isoprothiolane	ND	0,01	MOC3407
Isoproturon	ND	0,01	MOC3407
Isopyrazam	ND	0,01	MOC3407
Isoxaben	ND	0,01	MOC3407
Isoxaflutole(somme) (m)	ND		
Isoxaflutole	ND	0,01	MOC3407
RPA 202248	ND	0,01	MOC3407
Isoxathion	ND	0,01	MOC3407
Kresoxim-methyl	ND	0,01	MOC3407
Lenacil	ND	0,01	MOC3407
Linuron	ND	0,01	MOC3407
Lufenurone	ND	0,01	MOC3407
Mandipropamide	ND	0,01	MOC3407
Matrine	ND	0,01	MOC3407
MCPA+MCPB (m)	ND		
MCPA	ND	0,01	MOC3407
MCPB	ND	0,01	MOC3407
Mecarbam	ND	0,01	MOC3407
Mefenacet	ND	0,01	MOC3407
Mefentrifluconazole	ND	0,01	MOC3407
Mephosfolan	ND	0,01	MOC3407
Mesosulfuron-methyl	ND	0,01	MOC3407
Mesotrione	ND	0,01	MOC3407
Metaflumizone	ND	0,01	MOC3407
Metaldehyde	ND	0,01	MOC3407
Metamitron	ND	0,01	MOC3407
Metazachlor(somme)	ND		
Metazachlor ESA	ND	0,01	MOC3407
Metazachlor OA	ND	0,01	MOC3407
Metazachlor Metabolite 479M16	ND	0,01	MOC3407
Metconazole(Σ des isomères	ND	0,01	MOC3407
Methabenzthiazuron	ND	0,01	MOC3407
Methamidophos	ND	0,01	MOC3407
Methiocarbe(somme)	ND		
Methiocarbe	ND	0,01	MOC3407
Methiocarbe-sulfone	ND	0,01	MOC3407
Methiocarbe-sulfoxide	ND	0,01	MOC3407
Methomyl	ND	0,01	MOC3407
Methoxyfenozide	ND	0,01	MOC3407
Metobromuron	ND	0,01	MOC3407
Metolachlore ESA	ND	0,01	MOC3407
Metolachlore OA	ND	0,01	MOC3407
Metolcarb	ND	0,01	MOC3407
Metosulam	ND	0,01	MOC3407
Metoxuron	ND	0,01	MOC3407
Metrafenone	ND	0,01	MOC3407
Metribuzine	ND	0,01	MOC3407
Metsulfuron-methyl	ND	0,01	MOC3407

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Mevinphos	ND	0,01	MOC3407
Milbemectin(somme)	ND		
Milbemectin A3	ND	0,01	MOC3407
Milbemectin A4	ND	0,01	MOC3407
MNBA	ND	0,01	MOC3407
Molinate	ND	0,01	MOC3407
Monalide	ND	0,01	MOC3407
Monocrotophos	ND	0,01	MOC3407
Monolinuron	ND	0,01	MOC3407
Monuron	ND	0,01	MOC3407
NAD(1-naphtyl acetamide) (n	ND	0,01	MOC3407
Naled	ND	0,01	MOC3407
Napropamide	ND	0,01	MOC3407
Neburon	ND	0,01	MOC3407
Nicosulfuron	ND	0,01	MOC3407
Nitenpyram	ND	0,01	MOC3407
Norflurazon	ND	0,01	MOC3407
Novaluron	ND	0,01	MOC3407
Nuarimol	ND	0,01	MOC3407
Ofurace	ND	0,01	MOC3407
Omethoate	ND	0,01	MOC3407
Orthosulfamuron	ND	0,01	MOC3407
Oryzalin	ND	0,01	MOC3407
Oxamyl	ND	0,01	MOC3407
Oxasulfuron	ND	0,01	MOC3407
Oxathiapiprolin	ND	0,01	MOC3407
Oxymatrine	ND	0,01	MOC3407
Paclobutrazol	ND	0,01	MOC3407
Paraoxon-ethyl (m)	ND	0,01	MOC3407
Pebulate	ND	0,01	MOC3407
Pencycuron	ND	0,01	MOC3407
Penflufen	ND	0,01	MOC3407
Penoxsulame	ND	0,01	MOC3407
Penthiopyrad	ND	0,01	MOC3407
pethoxamid	ND	0,01	MOC3407
Phenmediphame	ND	0,01	MOC3407
Phorate(somme)	ND		
Phorate	ND	0,01	MOC3407
Phorate-sulfone	ND	0,01	MOC3407
Phorate-sulfoxide	ND	0,01	MOC3407
Phorate-oxon	ND	0,01	MOC3407
Phorate-oxon-sulfone	ND	0,01	MOC3407
Phorate-oxon-sulfoxide	ND	0,01	MOC3407
Phosmet(+oxon)	ND		
Phosmet	ND	0,01	MOC3407
Phosmet-oxon	ND	0,01	MOC3407
Phosphamidon	ND	0,01	MOC3407
Phoxim	ND	0,01	MOC3407
Picaridin	ND	0,01	MOC3407
Picolinafen	ND	0,01	MOC3407
Picoxystrobine	ND	0,01	MOC3407
Pinoxadene	ND	0,01	MOC3407
Pirimicarb-desmethyl	ND	0,01	MOC3407
Prallethrin	ND	0,01	MOC3407
Primisulfuron	ND	0,01	MOC3407
Prochloraz(somme) (m)	ND		
Prochloraz	ND	0,01	MOC3407
Prochloraz metabolite BTS9608	ND	0,01	MOC3407
Prochloraz metabolite BTS40348	ND	0,01	MOC3407
Prochloraz metabolite (BTS44595)	ND	0,01	MOC3407
Prochloraz metabolite BTS44596	ND	0,01	MOC3407
Promecarb	ND	0,01	MOC3407
Prometon	ND	0,01	MOC3407
Propamocarbe	ND	0,01	MOC3407
Propanil	ND	0,01	MOC3407
Propaphos	ND	0,01	MOC3407
Propaquizafop	ND	0,01	MOC3407
Propargite	ND	0,01	MOC3407
Propoxur	ND	0,01	MOC3407
Propoxycarbazone(somme)	ND		
Propoxycarbazone	ND	0,01	MOC3407
2-hydroxy-propoxycarbazo	ND	0,01	MOC3407
Prosulfuron	ND	0,01	MOC3407
Prothioconazole-desthio	ND	0,01	MOC3407
Pydiflumetofen	ND	0,01	MOC3407
Pymetrozine	ND	0,01	MOC3407
Pyraclofos	ND	0,01	MOC3407
Pyraclostrobine	ND	0,01	MOC3407
Pyraflufen-ethyl (m)	ND	0,01	MOC3407
Pyrethrines(Somme)	ND		
Cinerine I	ND	0,01	MOC3407
Cinerine II	ND	0,01	MOC3407
Jasmoline I	ND	0,01	MOC3407
Jasmoline II	ND	0,01	MOC3407
Pyrethrine I	ND	0,01	MOC3407
Pyrethrine II	ND	0,01	MOC3407
Pyridate(+Pyridafol) (m)	ND		
Pyridate	ND	0,01	MOC3407
Pyridafol	ND	0,01	MOC3407
Pyrimidifen	ND	0,01	MOC3407
Pyriofenone	ND	0,01	MOC3407
Pyroquilon	ND	0,01	MOC3407
Pyroxsulam	ND	0,01	MOC3407
Quinmerac	ND	0,01	MOC3407
Quinoclamine	ND	0,01	MOC3407
Quizalofop dont quizalofop-P	ND	0,01	MOC3407
Resmethrine	ND	0,01	MOC3407
Rimsulfuron	ND	0,01	MOC3407
Rotenone	ND	0,01	MOC3407
Sedaxane	ND	0,01	MOC3407
Silthiofam	ND	0,01	MOC3407
Simazine	ND	0,01	MOC3407
Simetryn	ND	0,01	MOC3407
Spinetoram XDE-175	ND		
Spinetoram XDE-175-J	ND	0,01	MOC3407
Spinetoram XDE-175-L	ND	0,01	MOC3407
Spinosad(A+D)	ND		
Spinosyne A	ND	0,01	MOC3407
Spinosyne D	ND	0,01	MOC3407
Spirodiclofen	ND	0,01	MOC3407
Spiromesifen	ND	0,01	MOC3407
Spirotetramate(+4 metabolite	ND		
Spirotetramat	ND	0,01	MOC3407
Spirotetramate-enol	ND	0,01	MOC3407
Spirotetramat-enol-glucosi	ND	0,01	MOC3407
Spirotetramat-keto-hydroxy	ND	0,01	MOC3407
Spirotetramat-mono-hydro	ND	0,01	MOC3407
Spiroxamine	ND	0,01	MOC3407
Sulcotrione	ND	0,01	MOC3407
Sulfosulfuron	ND	0,01	MOC3407
Sulfoxaflor	ND	0,01	MOC3407
TCMTB	ND	0,01	MOC3407
Tebufenozide	ND	0,01	MOC3407
Tebutam	ND	0,01	MOC3407
Tebuthiuron	ND	0,01	MOC3407
Teflubenzuron	ND	0,01	MOC3407
Tembotrione	ND	0,01	MOC3407
Tepraloxydim(somme) (m)	ND		
Tepraloxydim	ND	0,01	MOC3407
Tepraloxydim-5-hydroxy	ND	0,01	MOC3407
Terbumeton	ND	0,01	MOC3407
Terbumeton-desethyl	ND	0,01	MOC3407
Tetraconazole	ND	0,01	MOC3407
Thiabendazole	ND	0,01	MOC3407
Thiachlopride	ND	0,01	MOC3407
Thiadone	ND	0,01	MOC3407
Thiamethoxam	ND	0,01	MOC3407
Thiencarbazone-methyl	ND	0,01	MOC3407
Thifensulfuron-methyl	ND	0,01	MOC3407
Thiobencarb (m)	ND	0,01	MOC3407
Thiocyclam	ND	0,01	MOC3407
Thiodicarb	ND	0,01	MOC3407
Thiometon	ND	0,01	MOC3407
Thionazin	ND	0,01	MOC3407
Thiophanate-methyl	ND	0,01	MOC3407
Tolfenpyrad	ND	0,01	MOC3407
Topramezone	ND	0,01	MOC3407
Triasulfuron	ND	0,01	MOC3407
Triazamate	ND	0,01	MOC3407
Tribenuron-methyl	ND	0,01	MOC3407
Trichlorfon	ND	0,01	MOC3407
Triclopyr	ND	0,01	MOC3407
Tricyclazole	ND	0,01	MOC3407
Tridemorphe	ND	0,01	MOC3407
Trifloxystrobine	ND	0,01	MOC3407
Triflumuron	ND	0,01	MOC3407
Triflusulfuron Metabolite IN-M7222	ND	0,01	MOC3407
Triflusulfuron-methyl	ND	0,01	MOC3407
Triforine	ND	0,01	MOC3407
Trinexapac-ethyl	ND	0,01	MOC3407
Triticonazole	ND	0,01	MOC3407
Tritosulfuron	ND	0,01	MOC3407
Vamidothion	ND	0,01	MOC3407
Warfarin	ND	0,01	MOC3407

Specific monoresidues

	Result	LOQ	method
Unit ¤ : mg/kg			
AMPA	ND	0,01	MOC3/17
Dithiocarbamates (CS2)	ND	0,01	MOC3/11
Glyphosate	ND	0,01	MOC3/17

Heavy metals

	Result	LOQ	method
Unit ¤ : mg/kg			
Lead	0,045	0,04	MOC3/92
Cadmium	< 0,01	0,01	MOC3/92
Arsenic	< 0,03	0,03	MOC3/92
Mercury	< 0,005	0,005	MOC3/92

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Antimony	< 0,02	0,02	MOC3/92

Mycotoxines

	Result	LOQ	method
Unit ¤ : µg/kg			
Aflatoxin B1	ND	1	MOC3111
Aflatoxin B2	ND	1	MOC3111
Aflatoxin G1	ND	1	MOC3111
Aflatoxin G2	ND	1	MOC3111
Aflatoxins (Σ B1,B2, G1,G2)	ND	1	MOC3111
Ochratoxin A	ND	1	MOC3111
Zearalenon	ND	10	MOC3111
Deoxynivalenol	ND	50	MOC3111

Polycyclic aromatic hydrocarbons (PaH)

	Result	LOQ	method
Unit ¤ : µg/kg			
Benzo(a)pyrene	ND	0,5	MOC3/23
Benzo(a)anthracene	ND	0,5	MOC3/23
Benzo(b)fluoranthene	ND	0,5	MOC3/23
Chrysene	ND	0,5	MOC3/23
Sum of the 4 HAP	ND	0,5	MOC3/23

Other contaminants

	Result	LOQ	method
Unit ¤ : mg/kg			
Bromides	ND	5	MOC3/18

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EPI FRANCE
VALERIE BIZOT
3 RUE DE PREAUX
02130 VILLERS SUR FERE

Référence laboratoire	18/PN078234		
Référence client	Lot: 21180222 CHA		
Nature de l'échantillon	Ceramosides Powder Neutra	**Poids**	105,5g
Etat	Broyé	**Température à réception**	Ambiante
Date de réception	11/07/2018 09:57:23	**Limite de conservation**	11/08/2018
Echantillonnage	Client	**Transport**	TNT
Référence de devis	DPA180478	**Agence régionale**	Phytocontrol Paris_nord

Analyse demandée

Pesticides	1,4 Dichlorobenzene Liste spe PA170716/4 matrice complexe
Métaux lourds et ETM	Plomb Cadmium Arsenic Mercure Antimoine
Mycotoxines	Aflatoxines + Ochratoxine A + Deoxynivalenol (DON) + Zearalenone
Hydrocarbures aromatiques Polycycliques (HaP)	4 HAP

Echantillon à réception

Résultats d'analyses

	Résultat	Unité	LQ	Limite		Fin d'analyse
Pesticides						
Multirésidus GC 150						
Deltamethrine	0,022 ± 0,011	mg/kg	0,01			13/07/2018
Piperonyl butoxide	0,45 ± 0,16	mg/kg	0,01		(1)	13/07/2018
Liste 65 Californie numéro 1	ND					13/07/2018
Liste 65 Californie numéro 2	ND					13/07/2018
Monorésidus spécifiques						
Bromure de methyl CH3BR	ND	mg/kg	0,01			18/07/2018
1,3 dichloropropene	ND	mg/kg	0,01			18/07/2018
Dithiocarbamates (CS2)	ND	mg/kg	0,05			13/07/2018
Fentin (exprimé en cation triphenyletain)*	ND	mg/kg	0,01			16/07/2018
Nicotine	ND	mg/kg	0,01			12/07/2018
Pentachlorophenol	ND	mg/kg	0,01			13/07/2018
Métaux lourds et ETM						
Plomb*	< 0,04	mg/kg	0,04			12/07/2018
Cadmium*	< 0,01	mg/kg	0,01			12/07/2018
Arsenic*	< 0,03	mg/kg	0,03			12/07/2018
Mercure*	< 0,005	mg/kg	0,005			12/07/2018
Antimoine*	< 0,02	mg/kg	0,02			12/07/2018
Mycotoxines						
Aflatoxine B1	ND	µg/kg	1			12/07/2018
Aflatoxine B2	ND	µg/kg	1			12/07/2018
Aflatoxine G1	ND	µg/kg	1			12/07/2018
Aflatoxine G2	ND	µg/kg	1			12/07/2018
Aflatoxines (Σ B1,B2, G1,G2)	ND	µg/kg	1			12/07/2018
Ochratoxine A	ND	µg/kg	1			12/07/2018
Zearalenone	ND	µg/kg	10			12/07/2018
Deoxynivalenol	ND	µg/kg	50			12/07/2018
Hydrocarbures aromatiques Polycycliques (HaP)						
Benzo(a)pyrene	0,70 ± 0,14	µg/kg	0,5			12/07/2018
Benzo(a)anthracene	0,53 ± 0,11	µg/kg	0,5			12/07/2018
Benzo(b)fluoranthene	0,70 ± 0,14	µg/kg	0,5			12/07/2018
Chrysene	D < 0,5	µg/kg	0,5			12/07/2018
Somme des 4 HAP	1,9 ± 0,4	µg/kg	0,5			12/07/2018
Autres contaminants						
1,4-Dichlorobenzene	ND	mg/kg	0,1			24/07/2018

Détail des paramètres analysés et des méthodes utilisées en page(s) suivante(s)

Légende

ND = Non détecté D = Détecté LQ = Limite de Quantification NA = Non Analysé

(m):dosé(s) sans son(ses) analyte(s) associé(s) pour les analyses de résidus pesticides effectuées uniquement dans le champs d'application du règlement N°396/2005 et ses modifications, ou des directives 2006/125/CE et 2006/141/CE, ou pour les analyses de résidus médicamenteux effectuées uniquement dans le champs d'application du règlement 37/2010 et du guide CRL/2007.

Méthodes utilisées mentionnées en page(s) suivante(s) :

MOC3/05 version 0 : Détermination de la teneur en résidus de pesticides dans les produits non gras d'origine végétale ou animale par GC-MS(n) : méthode interne.
MOC3/09 version 0 : Détermination de la teneur en bromure de méthyle dans les produits non gras d'origine végétale par GC-MS/HS : méthode interne.
MOC3/11 version 0 : Détermination des résidus de dithiocarbamates dans les produits d'origine végétale par GC-MS/HS : méthode interne.
MOC3/23 version 2 : Détermination de la teneur en HAP par GC-MS/MS : méthode interne.
MOC3/25 version 8 : Détermination de la teneur en résidus de pesticides dans les produits non gras d'origine végétale par GC-MS(n) : méthode interne.
MOC3/31 version 0 : Détermination de la teneur en organoétains dans les produits non gras d'origine végétale par LC-MS(n) : méthode interne.
MOC3/33 version 0 : Détermination de la teneur en nicotine dans les produits non gras d'origine végétale par LC-MS-MS : méthode interne.
MOC3/49 version 0 : Détermination de la teneur en 1,3-Dichloropropène dans les produits non gras d'origine végétale par GC-MS(n): méthode interne.

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MOC3/68 version 0 : Détermination de la teneur en résidus de pesticides dans les produits d'origine végétale et animale par LC-MS(n): méthode interne.

MOC3/75 version 0 : Détermination de la teneur en 1, 1, 1, 2-Tetrafluoroethane, 1-Bromobutane, 1,2-Dichlorobenzene, 1,3-Dichlorobenzene et 1,4-Dichlorobenzenedans les produits d'origine végétale par GC-MS/HS: méthode interne.

MOC3/85 version 12 : Détermination de la teneur en métaux lourds et ETM (= Eléments Traces Métalliques) dans toutes denrées alimentaires d'origine animale ou végétale y compris la babyfood par ICP-MS: Méthode interne

MOC3111 version 2 : Détermination de la teneur en mycotoxines dans les produits d'origine végétale par LC-MS(n): méthode interne.

MOC3407 version 0 : Détermination de la teneur en pesticides par LC-MS-MS dans les produits non gras d'origine végétale : méthode interne

Commentaires

Les résultats analytiques ne sont valables que dans le périmètre du domaine d'application de la méthode utilisée.

Les valeurs limites indiquées sont issues des règlements et/ou des directives et/ou recommandations cités ci-dessous :

Pesticides

•Alimentation Humaine et Animale (matières premières) : Règlement (CE) N°396/2005 et ses modifications concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires et les aliments pour animaux d'origine végétale et animale.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Métaux lourds et ETM

•Alimentation Humaine :
Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
Cuivre et Mercure (selon matrice) : Règlement (CE) N°396/2005 et ses modifications concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires et les aliments pour animaux d'origine végétale et animale.
•Pour le vin : OIV - Limites maximales acceptables de divers éléments dans vin (édition 2015).
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.
•AdditifsalimentaRèglement (UE) N°231/2012 et ses modifications successives établissant les spécifications des additifs alimentaires énumérés aux annexes II et III du règlement (CE) n°1333/2008 du Parlement européen et du Conseil.

Mycotoxines

•Alimentation Humaine :
- Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
- Recommandations 2013/165/UE concernant la présence de toxines T-2 et HT-2 dans les céréales et les produits à base de céréales.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Hydrocarbures aromatiques Polycycliques (HaP)

•Alimentation Humaine :
Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
Selon la matrice, les résultats sont exprimés en µg/kg (matière brute) ou en µg/kg MG (matière grasse).

-Le résultat du paramètre Benzo(a)anthracene est corrigé par le rendement d'extraction qui est de : 111%.
-Le résultat du paramètre Benzo(a)pyrene est corrigé par le rendement d'extraction qui est de : 114%.
-Le résultat du paramètre Benzo(b)fluoranthene est corrigé par le rendement d'extraction qui est de : 105%.

(1) Le pipéronyl butoxide (PBO) est considéré comme un synergisant des pyrèthres naturels au niveau Européen, de ce fait aucune LMR communautaire n'est définie.
En revanche, pour les céréales cultivées en France, les autorités compétentes ont fixé une LMR nationale à 10mg/kg. Cette LMR ne s'applique pas aux céréales importées.
Dans le cadre de l'agriculture biologique, le CNAB (Comité National de l'Agriculture Biologique) a décidé dans sa réunion du 8 Décembre 2015, d'interdire toutes solutions phytosanitaires AB contenant du pipéronyl butoxyde sur le territoire français avec un délai de fin d'utilisation des stocks fixé au 30 Septembre 2017. En cas de détection en PBO, il convient de vous rapprocher de votre organisme certificateur.

informations complémentaires :

Deltamethrine : Inclut cis-deltamethrine.

Somme des 4 HAP : Somme de Benzo(a)pyrène, Benzo(a)anthracène, Benzo(b)fluoranthène et Chrysène.

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Signature

L'actualisation des données règlementaires est assurée par notre Service Veille Règlementaire dans le respect des dates de mise en application des textes européens ou autres référentiels publiés.

Rapport validé par :

Doriane BAUDOUIN
Validation Analytique

- Ce certificat produit et validé électroniquement fait foi. Le nom et la fonction des responsables sur ce document ont été produits sur base d'une procédure protégée et personnalisée. Une version papier de ce document paraphé peut être obtenue sur simple demande.
- Les résultats d'analyse ne concernent que les objets soumis à l'analyse.
- En l'absence de précision et d'indication contraire, la Limite de Détection est égale à la moitié de la Limite de Quantification (hors paramètres sous-traités).
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Pesticides

Multirésidus GC 150

FB3/02.a vers. 20 (18/06/2018)

	Résultat	LQ	méthode
Unité ◦ : mg/kg			
2,4,6 trichlorophenol (TCP) (m	ND	0,01	MOC3/05
2-Phenylphenol*	ND	0,01	MOC3/25
4,4-Dichlorobenzophenone	ND	0,01	MOC3/05
Acetochlore	ND	0,01	MOC3/05
Acibenzolar-S-methyl (m)	ND	0,01	MOC3/05
Aclonifen	ND	0,01	MOC3/05
Acrinathrine	ND	0,01	MOC3/05
Amisulbrom	ND	0,01	MOC3/05
Atrazine	ND	0,01	MOC3/05
Benalaxyl dont Benalaxyl-M*	ND	0,01	MOC3/25
Benfluraline	ND	0,01	MOC3/05
Bifenox	ND	0,01	MOC3/05
Bifenthrine (∑ des isomères)*	ND	0,01	MOC3/25
Biphenyl	ND	0,01	MOC3/05
Bromopropylate*	ND	0,01	MOC3/25
Butraline	ND	0,01	MOC3/05
Captan(+THPI)	ND		
Captan	ND	0,01	MOC3/05
Tetrahydrophtalimide (THP	ND	0,01	MOC3/05
Carbofuran(somme) (m)	ND		
Carbofuran	ND	0,01	MOC3/05
Carbofuran-3-Hydroxy	ND	0,01	MOC3/05
Furathiocarbe	ND	0,01	MOC3/05
Carfentrazone-ethyl*	ND	0,01	MOC3/25
Chlordane(cis+trans)	ND	0,01	MOC3/05
Chlorfenapyr	ND	0,01	MOC3/05
Chlorfenvinphos*	ND	0,01	MOC3/25
Chlorobenzilate*	ND	0,01	MOC3/25
Chlorothalonil	ND	0,01	MOC3/05
Chlorprophame*	ND	0,01	MOC3/25
Chlorpyrifos*	ND	0,01	MOC3/25
Chlorpyrifos-methyl*	ND	0,01	MOC3/25
Clomazone	ND	0,01	MOC3/05
Coumaphos	ND	0,01	MOC3/05
Cyfluthrine (β+γ)	ND	0,01	MOC3/05
Cyhalofop-butyl	ND	0,01	MOC3/05
Cyhalothrine(lambda)*	ND	0,01	MOC3/25
Cypermethrine(α+β+θ+ζ)	ND	0,01	MOC3/05
Cyproconazole*	ND	0,01	MOC3/25
Cyprodinil*	ND	0,01	MOC3/25
DDT(somme)	ND		
o,p'-DDT	ND	0,01	MOC3/05
p,p'-DDT*	ND	0,01	MOC3/25
p,p'-DDE*	ND	0,01	MOC3/25
p,p'-TDE(DDD)	ND	0,01	MOC3/05
Deltamethrine	0,022	0,01	MOC3/05
Dichlofenthion*	ND	0,01	MOC3/25
Dichlorvos	ND	0,01	MOC3/05
Diclofop-methyl* (m)	ND	0,01	MOC3/25
Dicofol(Σ des isomères)	ND		
Dicofol o,p'	ND	0,01	MOC3/05
Dicofol p,p'	ND	0,01	MOC3/05
Dieldrin(+Aldrin)	ND		
Dieldrin	ND	0,01	MOC3/05
Aldrin	ND	0,01	MOC3/05
Diethofencarb	ND	0,01	MOC3/05
Difenoconazole*	ND	0,01	MOC3/25
Diflufenican	ND	0,01	MOC3/05
Diphenylamine*	ND	0,01	MOC3/25
Endosulfan (somme)	ND		
Endosulfan α	ND	0,01	MOC3/05
Endosulfan β	ND	0,01	MOC3/05
Endosulfan sulfate	ND	0,01	MOC3/05
Ethion	ND	0,01	MOC3/05
Ethofumesate (m)	ND	0,01	MOC3/05
Ethoprophos*	ND	0,01	MOC3/25
Ethoxyquine	ND	0,01	MOC3/05
Etofenprox	ND	0,01	MOC3/05
Etridiazole	ND	0,01	MOC3/05
Famoxadone	ND	0,01	MOC3/05
Fenamiphos (m)	ND	0,01	MOC3/05
Fenarimol*	ND	0,01	MOC3/25
Fenazaquin	ND	0,01	MOC3/05
Fenhexamide*	ND	0,01	MOC3/25
Fenitrothion	ND	0,01	MOC3/05
Fenobucarbe	ND	0,01	MOC3/05
Fenpropathrine	ND	0,01	MOC3/05
Fenpropimorphe (∑ des isomères)	ND	0,01	MOC3/05
Fenvalerate (Σ des isomères)	ND	0,01	MOC3/05
Fipronil(somme)	ND		
Fipronil	ND	0,005	MOC3/05
Fipronil-sulfone	ND	0,005	MOC3/05
Fluazifop-p-butyl (m)	ND	0,01	MOC3/05
Fludioxonil*	ND	0,01	MOC3/25
Flufenacet (m)	ND	0,01	MOC3/05
Fluopicolide	ND	0,01	MOC3/05
Flurochloridone	ND	0,01	MOC3/05
Fluroxypyr-methylheptyl ester (m)	ND	0,01	MOC3/05
Flusilazole*	ND	0,01	MOC3/25
Flutolanil	ND	0,01	MOC3/05
Flutriafol	ND	0,01	MOC3/05
Fluvalinate (Tau)	ND	0,01	MOC3/05
Folpet(+Phtalimide)	ND		
Folpet	ND	0,01	MOC3/05
Phtalimide	ND	0,01	MOC3/05
Fonofos*	ND	0,01	MOC3/25
Haloxyfop-2-ethoxyethyl (m)	ND	0,01	MOC3/05
Haloxyfop-methyl(R+S) (m)	ND	0,01	MOC3/05
HCB*	ND	0,01	MOC3/25
HCH(α+β+δ+e)	ND		
HCH alpha*	ND	0,01	MOC3/25
HCH beta*	ND	0,01	MOC3/25
HCH delta*	ND	0,01	MOC3/25
HCH epsilon	ND	0,01	MOC3/05
HCH gamma	ND	0,01	MOC3/05
Heptachlore(somme)	ND		
Heptachlore	ND	0,01	MOC3/05
Heptachlore epoxyde cis-	ND	0,01	MOC3/05
Heptachlore epoxyde trans-	ND	0,01	MOC3/05
Iprodione	ND	0,01	MOC3/05
Malathion(+Malaoxon)	ND		
Malathion*	ND	0,01	MOC3/25
Malaoxon	ND	0,01	MOC3/05
Mepanipyrim*	ND	0,01	MOC3/25
Metalaxyl dont Metalaxyl-M	ND	0,01	MOC3/05
Metazachlor (m)	ND	0,01	MOC3/05
Methidathion	ND	0,01	MOC3/05
Methoxychlore	ND	0,01	MOC3/05
Metolachlore dont S-Metolachlore	ND	0,01	MOC3/05
Myclobutanil*	ND	0,01	MOC3/25
Oxadiazon*	ND	0,01	MOC3/25
Oxadixyl*	ND	0,01	MOC3/25
Oxyfluorfene	ND	0,01	MOC3/05
Penconazole*	ND	0,01	MOC3/25
Pendimethaline	ND	0,01	MOC3/05
Permethrine(cis + trans)	ND	0,01	MOC3/05
Phosalone*	ND	0,01	MOC3/25
Piperonyl butoxide	0,45	0,01	MOC3/05
Pirimicarb*	ND	0,01	MOC3/25
Pirimiphos-ethyl	ND	0,01	MOC3/05
Pirimiphos-methyl*	ND	0,01	MOC3/25
Procymidone*	ND	0,01	MOC3/25
Profenophos	ND	0,01	MOC3/05
Prometryn	ND	0,01	MOC3/05
Propiconazole*	ND	0,01	MOC3/25
Propyzamide*	ND	0,01	MOC3/25
Proquinazid*	ND	0,01	MOC3/25
Prosulfocarbe	ND	0,01	MOC3/05
Pyridaben	ND	0,01	MOC3/05
Pyridalyl	ND	0,01	MOC3/05
Pyrimethanil*	ND	0,01	MOC3/25
Pyriproxyfen*	ND	0,01	MOC3/25
Quinoxyfen	ND	0,01	MOC3/05
Quintozene(+PCA)	ND		
Quintozene	ND	0,01	MOC3/05
Pentachloroaniline (PCA)	ND	0,01	MOC3/05
Quizalofop-ethyl	ND	0,01	MOC3/05
Tebuconazole*	ND	0,01	MOC3/25
Tebufenpyrad*	ND	0,01	MOC3/25
Tefluthrine	ND	0,01	MOC3/05
Terbuthylazine	ND	0,01	MOC3/05
Tetramethrine	ND	0,01	MOC3/05
Tolclofos-methyl*	ND	0,01	MOC3/25
Tolylfluanid (m)	ND	0,01	MOC3/05
Triadimefon*	ND	0,01	MOC3/25
Triadimenol*	ND	0,01	MOC3/25
Triazophos	ND	0,01	MOC3/05
Trifluraline	ND	0,01	MOC3/05
Valifenalate	ND	0,01	MOC3/05
Vinclozoline*	ND	0,01	MOC3/25
Zoxamide	ND	0,01	MOC3/05

Liste 65 Californie numéro 1

	Résultat	LQ	méthode
Unité ◦ : mg/kg			
Alachlore	ND	0,01	MOC3/05
Carbaryl	ND	0,01	MOC3/05
Diuron	ND	0,01	MOC3407
Fenoxycarbe	ND	0,01	MOC3407
Imazalil	ND	0,01	MOC3407
Methomyl	ND	0,01	MOC3407
Oryzalin	ND	0,01	MOC3407

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Propachlore (m)	ND	0,01	MOC3/05
Propargite	ND	0,01	MOC3407
Propoxur	ND	0,01	MOC3407
Thiodicarb	ND	0,01	MOC3407

Liste 65 Californie numéro 2

	Résultat	LQ	méthode
Unité ⇳ : mg/kg			
2,4 DB (m)	ND	0,01	MOC3/68
Abamectine(somme)	ND		
Amitraze	ND	0,01	MOC3407
Bromacil	ND	0,01	MOC3407
Bromoxynil-octanoate	ND	0,01	MOC3/05
Carbendazime(+Benomyl)	ND	0,01	MOC3407
Cyanazine	ND	0,01	MOC3407
Oxydemeton-methyl	ND	0,01	MOC3407
Dinocap(Σ des isomères) (m)	ND	0,01	MOC3407
Dinoseb (m)	ND	0,01	MOC3407
EPTC	ND	0,01	MOC3407
Fenoxaprop-ethyl	ND	0,01	MOC3407
Fluazifop(acide libre) (m)	ND	0,01	MOC3407
Hydramethylnon	ND	0,01	MOC3407
Linuron	ND	0,01	MOC3407
Molinate	ND	0,01	MOC3407
Resmethrine	ND	0,01	MOC3407
Thiophanate-methyl	ND	0,01	MOC3407
Warfarin	ND	0,01	MOC3407

Monorésidus spécifiques

	Résultat	LQ	méthode
Unité ⇳ : mg/kg			
Bromure de methyl CH3BR	ND	0,01	MOC3/09
1,3 dichloropropene	ND	0,01	MOC3/49
Dithiocarbamates (CS2)	ND	0,05	MOC3/11
Fentin (exprimé en cation triphenyletain)*	ND	0,01	MOC3/31
Nicotine	ND	0,01	MOC3/33
Pentachlorophenol	ND	0,01	MOC3/05

Métaux lourds et ETM

	Résultat	LQ	méthode
Unité ⇳ : mg/kg			
Plomb*	< 0,04	0,04	MOC3/85
Cadmium*	< 0,01	0,01	MOC3/85
Arsenic*	< 0,03	0,03	MOC3/85
Mercure*	< 0,005	0,005	MOC3/85
Antimoine*	< 0,02	0,02	MOC3/85

Mycotoxines

	Résultat	LQ	méthode
Unité ⇳ : µg/kg			
Aflatoxine B1	ND	1	MOC3111
Aflatoxine B2	ND	1	MOC3111
Aflatoxine G1	ND	1	MOC3111
Aflatoxine G2	ND	1	MOC3111
Aflatoxines (Σ B1,B2, G1,G2)	ND	1	MOC3111
Ochratoxine A	ND	1	MOC3111
Zearalenone	ND	10	MOC3111
Deoxynivalenol	ND	50	MOC3111

Hydrocarbures aromatiques Polycycliques (HaP)

	Résultat	LQ	méthode
Unité ⇳ : µg/kg			
Benzo(a)pyrene	0,70	0,5	MOC3/23
Benzo(a)anthracene	0,53	0,5	MOC3/23
Benzo(b)fluoranthene	0,70	0,5	MOC3/23
Chrysene	D < 0,5	0,5	MOC3/23
Somme des 4 HAP	1,9	0,5	MOC3/23

Autres contaminants

	Résultat	LQ	méthode
Unité ⇳ : mg/kg			
1,4-Dichlorobenzene	ND	0,1	MOC3/75

Phytocontrol
Laboratoire d'analyses

ISO 14001

EPI FRANCE
VALERIE BIZOT
3 RUE DE PREAUX
02130 VILLERS SUR FERE

Référence laboratoire	17/PN48826		
Référence client	Lot: 21170530CHA		
Nature de l'échantillon	ceramosides powder neutra	**Poids**	102,8g
Etat	Broyé	**Température à réception**	Ambiante
Date de réception	09/06/2017 09:27:50	**Limite de conservation**	09/07/2017
Echantillonnage	Client	**Transport**	TNT
Référence de devis	DPA160330	**Agence régionale**	Phytocontrol Paris_nord

Analyse demandée

Pesticides	Multirésidus GC150
Métaux lourds et ETM	Plomb Cadmium Arsenic Mercure Antimoine
Mycotoxines	Aflatoxines + Ochratoxine A + Deoxynivalenol (DON) + Zearalenone
Autres contaminants	4 HAP

Echantillon à réception

Résultats d'analyses

	Résultat	Unité	LQ	Limite	Fin d'analyse
Pesticides					
Multirésidus GC 150					
Chlorpyrifos-methyl	0,031 ± 0,016	mg/kg	0,01		12/06/2017
Piperonyl butoxide	0,17 ± 0,07	mg/kg	0,01		12/06/2017
Métaux lourds et ETM					
Plomb	< 0,04	mg/kg	0,04		12/06/2017
Cadmium	< 0,01	mg/kg	0,01		12/06/2017
Arsenic	< 0,03	mg/kg	0,03		12/06/2017
Mercure	< 0,005	mg/kg	0,005		12/06/2017
Antimoine	< 0,02	mg/kg	0,02		12/06/2017
Mycotoxines					
Aflatoxine B1	ND	µg/kg	1		12/06/2017
Aflatoxine B2	ND	µg/kg	1		12/06/2017
Aflatoxine G1	ND	µg/kg	1		12/06/2017
Aflatoxine G2	ND	µg/kg	1		12/06/2017
Aflatoxines (Σ B1,B2, G1,G2)	ND	µg/kg	4		12/06/2017
Ochratoxine A	ND	µg/kg	1		12/06/2017
Zearalenone	ND	µg/kg	10		12/06/2017
Deoxynivalenol	ND	µg/kg	50		12/06/2017
Hydrocabures aromatiques Polycycliques (HaP)					
Somme des 4 HAP	ND	µg/kg	0,5		12/06/2017
Benzo(a)anthracene	ND	µg/kg	0,5		12/06/2017
Benzo(a)pyrene	ND	µg/kg	0,5		12/06/2017
Benzo(b)fluoranthene	ND	µg/kg	0,5		12/06/2017
Chrysene	ND	µg/kg	0,5		12/06/2017

Détail des paramètres analysés et des méthodes utilisées en page(s) suivante(s)

Légende

ND = Non détecté D = Détecté LQ = Limite de Quantification NA = Non Analysé

(m):dosé(s) sans son(ses) analyte(s) associé(s) pour les analyses effectuées uniquement dans le champs d'application du règlement N°396/2005 et ses modifications ou des directives 2006/125/CE et 2006/141/CE.

Méthodes utilisées mentionnées en page(s) suivante(s) :

MOC3/05 version 0 : Détermination de la teneur en résidus de pesticides dans les produits non gras d'origine végétale ou animale par GC-MS(n) : méthode interne.

MOC3/14 version 0 : Détermination de la teneur en HAP par GC-MS(n) et/ou UFLC : méthode interne.

MOC3/92 version 10 : Détermination de la teneur en métaux lourds et ETM (= Eléments Traces Métalliques) dans toutes denrées alimentaires d'origine animale ou végétale y compris la babyfood par ICP-MS: Méthode interne

MOC3111 version 2 : Détermination de la teneur en mycotoxines dans les produits d'origine végétale par UFLC: méthode interne.

Commentaires

Les résultats analytiques ne sont valables que dans le périmètre du domaine d'application de la méthode utilisée.

Les valeurs limites indiquées sont issues des règlements et/ou des directives et/ou recommandations cités ci-dessous :

Pesticides

•Alimentation Humaine et Animale (matières premières) : Règlement (CE) N°396/2005 et ses modifications concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires et les aliments pour animaux d'origine végétale et animale.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.

Métaux lourds et ETM

•Alimentation Humaine :
Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
•Pour le vin : OIV - Limites maximales acceptables de divers éléments dans vin (édition 2015).
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent aux aliments pour animaux d'une teneur en humidité de 12%.
•Additifs alimentaires : Règlement (UE) N°231/2012 et ses modifications successives établissant les spécifications des additifs alimentaires énumérés aux annexes II et III du règlement (CE) n°1333/2008 du Parlement européen et du Conseil.

Mycotoxines

•Alimentation Humaine :
- Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
- Recommandations 2013/165/UE concernant la présence de toxines T-2 et HT-2 dans les céréales et les produits à base de céréales.
•Alimentation Animale : Directive 2002/32 et ses modifications concernant les substances indésirables dans les aliments pour animaux. Les teneurs maximales s'appliquent

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aux aliments pour animaux d'une teneur en humidité de 12%.

Hydrocabures aromatiques Polycycliques (HaP)

•Alimentation Humaine :
Règlement (CE) N°1881/2006 et ses modifications portant fixation de teneurs maximales pour certains contaminants dans les denrées alimentaires.
Selon la matrice, les résultats sont exprimés en µg/kg (matière brute) ou en µg/kg MG (matière grasse).

Signature

L'actualisation des données règlementaires est assurée par notre Service Veille Règlementaire dans le respect des dates de mise en application des textes européens ou autres référentiels publiés.

Rapport validé par :

David SANCHEZ

- Ce certificat produit et validé électroniquement fait foi. Le nom et la fonction des responsables sur ce document ont été produits sur base d'une procédure protégée et personnalisée. Une version papier de ce document paraphé peut être obtenue sur simple demande.
- Les résultats d'analyse ne concernent que les objets soumis à l'analyse.
- En l'absence de précision et d'indication contraire, la Limite de Détection est égale à la moitié de la Limite de Quantification (hors paramètres sous-traités).
- La reproduction de ce rapport n'est autorisée que sous sa forme intégrale sauf autorisation du laboratoire.
- Phytocontrol est agréé par l'AFSCA, habilité par l'INAO et le QS et est certifié ISO 14001 par l'Afnor.

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Pesticides

Multirésidus GC 150

FB3/02.a vers. 14 (18/04/2017)

Unité ◊ : mg/kg	Résultat	LQ	méthode
2-Phenylphenol	ND	0,01	MOC3/05
3,4-dichloroaniline	ND	0,01	MOC3/05
4,4-Dichlorobenzophenone	ND	0,01	MOC3/05
Acibenzolar-S-methyl (m)	ND	0,01	MOC3/05
Aclonifen	ND	0,01	MOC3/05
Acrinathrine	ND	0,01	MOC3/05
Atrazine	ND	0,01	MOC3/05
Benalaxyl dont Benalaxyl-M	ND	0,01	MOC3/05
Benfluraline	ND	0,01	MOC3/05
Bifenox	ND	0,01	MOC3/05
Bifenthrine	ND	0,01	MOC3/05
Biphenyl	ND	0,01	MOC3/05
Bitertanol	ND	0,01	MOC3/05
Bromopropylate	ND	0,01	MOC3/05
Butachlor	ND	0,01	MOC3/05
Butraline	ND	0,01	MOC3/05
Captan(+THPI)	ND		
Captan	ND	0,01	MOC3/05
Tetrahydrophtalimide (THPI)	ND	0,01	MOC3/05
Carbofuran(+3-hydroxy)+Furathiocarb (m)	ND		
Carbofuran	ND	0,01	MOC3/05
Carbofuran-3-Hydroxy	ND	0,01	MOC3/05
Furathiocarbe	ND	0,01	MOC3/05
Carfentrazone-ethyl	ND	0,01	MOC3/05
Chlordane(cis+trans)	ND	0,01	MOC3/05
Chlorfenvinphos	ND	0,01	MOC3/05
Chlorobenzilate	ND	0,01	MOC3/05
Chlorothalonil	ND	0,01	MOC3/05
Chlorprophame	ND	0,01	MOC3/05
Chlorpyrifos	ND	0,01	MOC3/05
Chlorpyrifos-methyl	0,031	0,01	MOC3/05
Chlorthal dimethyl	ND	0,01	MOC3/05
Clomazone	ND	0,01	MOC3/05
Coumaphos	ND	0,01	MOC3/05
Cyfluthrine (β+γ)	ND	0,01	MOC3/05
Cyhalofop-butyl	ND	0,01	MOC3/05
Cyhalothrine(lambda)	ND	0,01	MOC3/05
Cymiazole	ND	0,01	MOC3/05
Cypermethrine(α+β+θ+ζ)	ND	0,01	MOC3/05
Cyproconazole	ND	0,01	MOC3/05
Cyprodinil	ND	0,01	MOC3/05
DDT(Σ des isomères)	ND		
o,p'-DDT	ND	0,01	MOC3/05
p,p'-DDT	ND	0,01	MOC3/05
p,p'-DDE	ND	0,01	MOC3/05
p,p'-TDE(DDD)	ND	0,01	MOC3/05
Deltamethrine	ND	0,01	MOC3/05
Diazinon	ND	0,01	MOC3/05
Dichlofenthion	ND	0,01	MOC3/05
Dichlorvos	ND	0,01	MOC3/05
Diclofop-methyl (m)	ND	0,01	MOC3/05
Dicofol(Σ des isomères)	ND		
Dicofol o,p'	ND	0,01	MOC3/05
Dicofol p,p'	ND	0,01	MOC3/05
Dieldrin(+Aldrin)	ND		
Dieldrin	ND	0,01	MOC3/05
Aldrin	ND	0,01	MOC3/05
Diethofencarb	ND	0,01	MOC3/05
Difenoconazole	ND	0,01	MOC3/05
Diflufenican	ND	0,01	MOC3/05
Diphenylamine	ND	0,01	MOC3/05
Endosulfan (α+β+sulfate)	ND		
Endosulfan α	ND	0,01	MOC3/05
Endosulfan β	ND	0,01	MOC3/05
Endosulfan sulfate	ND	0,01	MOC3/05
Ethion	ND	0,01	MOC3/05
Ethofumesate (m)	ND	0,01	MOC3/05
Ethoprophos	ND	0,01	MOC3/05
Ethoxyquine	ND	0,01	MOC3/05
Etofenprox	ND	0,01	MOC3/05
Etridiazole	ND	0,01	MOC3/05
Famoxadone	ND	0,01	MOC3/05
Fenamiphos (m)	ND	0,01	MOC3/05
Fenarimol	ND	0,01	MOC3/05
Fenazaquin	ND	0,01	MOC3/05
Fenchlorphos(+oxon)	ND		
Fenchlorphos	ND	0,01	MOC3/05
Fenchlorphos oxon	ND	0,01	MOC3/05
Fenhexamide	ND	0,01	MOC3/05
Fenitrothion	ND	0,01	MOC3/05
Fenoxaprop-ethyl	ND	0,01	MOC3/05
Fenoxycarbe	ND	0,01	MOC3/05
Fenpropathrine	ND	0,01	MOC3/05
Fenpropidine	ND	0,01	MOC3/05
Fenpropimorphe	ND	0,01	MOC3/05
Fenthion(+sulfone+sulfoxide) (m)	ND		
Fenthion	ND	0,01	MOC3/05
Fenthion-sulfone	ND	0,01	MOC3/05
Fenthion-sulfoxide	ND	0,01	MOC3/05
Fenvalerate (Σ des isomères)	ND	0,01	MOC3/05
Fipronil(+sulfone)	ND		
Fipronil	ND	0,005	MOC3/05
Fipronil-sulfone	ND	0,005	MOC3/05
Fipronil-desulfinyl	ND	0,01	MOC3/05
Fluazifop-p-butyl (m)	ND	0,01	MOC3/05
Flucythrinate	ND	0,01	MOC3/05
Fludioxonil	ND	0,01	MOC3/05
Flufenacet (m)	ND	0,01	MOC3/05
Fluopicolide	ND	0,01	MOC3/05
Flurochloridone	ND	0,01	MOC3/05
Fluroxypyr-methylheptyl ester (m)	ND	0,01	MOC3/05
Flusilazole	ND	0,01	MOC3/05
Flutolanil	ND	0,01	MOC3/05
Flutriafol	ND	0,01	MOC3/05
Fluvalinate (Tau)	ND	0,01	MOC3/05
Folpet(+Phtalimide)	ND		
Folpet	ND	0,01	MOC3/05
Phtalimide	ND	0,01	MOC3/05
Fonofos	ND	0,01	MOC3/05
Haloxyfop-2-ethoxyethyl (m)	ND	0,01	MOC3/05
Haloxyfop-methyl(R+S) (m)	ND	0,01	MOC3/05
HCB	ND	0,01	MOC3/05
HCH(α+β+δ+e)	ND		
HCH alpha	ND	0,01	MOC3/05
HCH beta	ND	0,01	MOC3/05
HCH delta	ND	0,01	MOC3/05
HCH epsilon	ND	0,01	MOC3/05
HCH gamma	ND	0,01	MOC3/05
Heptachlore(+epoxyde)	ND		
Heptachlore	ND	0,01	MOC3/05
Heptachlore epoxyde cis-	ND	0,01	MOC3/05
Heptachlore epoxyde trans-	ND	0,01	MOC3/05
Hexaconazole	ND	0,01	MOC3/05
Iprodione	ND	0,01	MOC3/05
Isoxadifen-ethyl	ND	0,01	MOC3/05
Isoxaflutole (m)	ND	0,01	MOC3/05
Malathion(+Malaoxon)	ND		
Malathion	ND	0,01	MOC3/05
Malaoxon	ND	0,01	MOC3/05
Mepanipyrim	ND	0,01	MOC3/05
Metalaxyl dont Metalaxyl-M	ND	0,01	MOC3/05
Metazachlor (m)	ND	0,01	MOC3/05
Methidathion	ND	0,01	MOC3/05
Methiocarbe (m)	ND	0,01	MOC3/05
Methoxychlore	ND	0,01	MOC3/05
Metolachlore dont S-Metolachlore	ND	0,01	MOC3/05
Metribuzine	ND	0,01	MOC3/05
Monalide	ND	0,01	MOC3/05
Myclobutanil	ND	0,01	MOC3/05
Napropamide	ND	0,01	MOC3/05
Oxadiazon	ND	0,01	MOC3/05
Oxadixyl	ND	0,01	MOC3/05
Oxyfluorfene	ND	0,01	MOC3/05
Parathion-ethyl	ND	0,01	MOC3/05
Parathion-methyl (m)	ND	0,01	MOC3/05
Penconazole	ND	0,01	MOC3/05
Pendimethaline	ND	0,01	MOC3/05
Permethrine(cis + trans)	ND	0,01	MOC3/05
Phosalone	ND	0,01	MOC3/05
Piperonyl butoxide	0,17	0,01	MOC3/05
Pirimicarb	ND	0,01	MOC3/05
Pirimiphos-ethyl	ND	0,01	MOC3/05
Pirimiphos-methyl	ND	0,01	MOC3/05
Prochloraz(+TCP) (m)	ND		
Prochloraz	ND	0,01	MOC3/05
2,4,6 trichlorophenol (TCP)	ND	0,01	MOC3/05
Procymidone	ND	0,01	MOC3/05
Profenophos	ND	0,01	MOC3/05
Propiconazole	ND	0,01	MOC3/05
Propyzamide	ND	0,01	MOC3/05
Proquinazid	ND	0,01	MOC3/05
Prosulfocarbe	ND	0,01	MOC3/05
Pyridaben	ND	0,01	MOC3/05
Pyridalyl	ND	0,01	MOC3/05
Pyridaphenthion	ND	0,01	MOC3/05
Pyrimethanil	ND	0,01	MOC3/05
Pyriproxyfen	ND	0,01	MOC3/05
Quinoxyfen	ND	0,01	MOC3/05
Quintozene(+PCA)	ND		
Quintozene	ND	0,01	MOC3/05
Pentachloroaniline (PCA)	ND	0,01	MOC3/05
Quizalofop-ethyl	ND	0,01	MOC3/05
S 421	ND	0,01	MOC3/05

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S.A.S. au Capital de 1.000.000 euros - SIRET 490 024 049 00028 RCS Nîmes - TVA intracom FR08490024049 - APE 7120B

Sebuthylazine	ND	0,01	MOC3/05
Tebuconazole	ND	0,01	MOC3/05
Tebufenpyrad	ND	0,01	MOC3/05
Tebupirimphos	ND	0,01	MOC3/05
Tefluthrine	ND	0,01	MOC3/05
Terbufos	ND	0,01	MOC3/05
Terbuthylazine	ND	0,01	MOC3/05
Tetramethrine	ND	0,01	MOC3/05
Tolclofos-methyl	ND	0,01	MOC3/05
Tolylfluanid (m)	ND	0,01	MOC3/05
Triadimefone+Triadimenol	ND		
Triadimefon	ND	0,01	MOC3/05
Triadimenol	ND	0,01	MOC3/05
Triazophos	ND	0,01	MOC3/05
Trifluraline	ND	0,01	MOC3/05
Valifenalate	ND	0,01	MOC3/05
Vinclozoline	ND	0,01	MOC3/05
Zoxamide	ND	0,01	MOC3/05

Métaux lourds et ETM

	Résultat	LQ	méthode
Unité ◊ : mg/kg			
Plomb	< 0,04	0,04	MOC3/92
Cadmium	< 0,01	0,01	MOC3/92
Arsenic	< 0,03	0,03	MOC3/92
Mercure	< 0,005	0,005	MOC3/92
Antimoine	< 0,02	0,02	MOC3/92

Mycotoxines

	Résultat	LQ	méthode
Unité ◊ : µg/kg			
Aflatoxine B1	ND	1	MOC3111
Aflatoxine B2	ND	1	MOC3111
Aflatoxine G1	ND	1	MOC3111
Aflatoxine G2	ND	1	MOC3111
Aflatoxines (Σ B1,B2, G1,G2)	ND	4	MOC3111
Ochratoxine A	ND	1	MOC3111
Zearalenone	ND	10	MOC3111
Deoxynivalenol	ND	50	MOC3111

Hydrocabures aromatiques Polycycliques (HaP)

	Résultat	LQ	méthode
Unité ◊ : µg/kg			
Somme des 4 HAP	ND	0,5	MOC3/14
Benzo(a)anthracene	ND	0,5	MOC3/14
Benzo(a)pyrene	ND	0,5	MOC3/14
Benzo(b)fluoranthene	ND	0,5	MOC3/14
Chrysene	ND	0,5	MOC3/14

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Statement Heavy metals quantification with validated method CERAMOSIDES™ POWDER NEUTRA

Heavy metals are quantified in an external laboratory using an internal method based on NF EN 15763 method by ICP-MS.

We hereby certify that this internal method used had been validated on the matrix CERAMOSIDES™ POWDER NEUTRA.

Fait à VILLERS SUR FERE,
Le 20/05/2020

Valérie BIZOT
Quality Manager

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SARL au capital de 45 000 € RCS SOISSONS B 414 332 817 SIRET : 414 332 817 00025 – APE : 1041 A – N° TVA FR 144 14 332 817

BULLETIN DE CONTROLE
CERTIFICATE OF ANALYSIS
Fabriqué le / *Date of manufacture*: 23/12/2019 – *12/23/2019*
Date de péremption / *Expiry date*: 23/12/2022 – *12/23/2022*

Nom commercial / *Comercial name*: CERAMOSIDES™ OIL NEUTRA
Description du produit / *Product description*: Wheat seed oil
Origine (Genre/Espèce) / *Origin (Genus/Species)*: Blé / *Wheat (Triticum sativum, synonymous vulgare, aestivum)*
Partie de la plante utilisée / *Plant Part Used*: Grain / *Seed*
Lot / *Batch*: 411191223

	SPECIFICATIONS *SPECIFICATIONS*	**CONTROLE** *CONTROL*	**METHODES** *METHODES*
CARACTERISTIQUES ORGANOLEPTIQUES / *ORGANOLEPTIC DATAS*			
- Aspect / *aspect* [1]	Huile visqueuse/*viscous oil*	**Conforme / *conform***	Internes: visuelles et olfactives / Internal : visual and olfactive
- Couleur / *color* [1]	Marron à marron clair / *brown to light brown*	**Conforme / *conform***	
- Odeur / *odour* [1]	Caractéristique de céréales / *cereals characteristic*	**Conforme / *conform***	
CONTROLES PHYSICO-CHIMIQUES / *PHYSICO-CHEMICAL DATAS*			
- Teneur en actifs / *Active ingredients content* [1]	Sphingolipides totaux dont glycosphingolipides/ *Total sphingolipids including glycosphingolipids* ≥ 15 %	**30.8**	Internal ref 06520-V3
	DGDG ≥ 15 %	**18.9**	Internal ref 06522-V4
- Azote total lié aux lipides polaires / *total nitrogen linked to polar lipids* [1]	≥ 0.2 %	**0.3**	Internal adapted from Dumas NF EN ISO 16634-1 – 12/2008
- Indice d'acide / *acid value* [1]	< 20 mg KOH/g	**13.1**	NF EN ISO 660 – 09/2009
- Indice de peroxyde / *peroxide value* [1]	< 10 mEq/kg	**< 0.1**	NF EN ISO 3960 – 06/2010
- Perte à la dessication / *loss on drying* [1]	< 5 %	**0.9**	NF EN ISO 662 – 02/2001
- Extrait sec / *dry extract* [1]	> 95 %	**98.1**	NF EN ISO 662 – 02/2001
- Identification des lipides polaires (CCM)/ *polar lipids identification (TLC)* [2]	Identique à celui du témoin / *Identical to the assay*	**Conforme / *conform***	Internal ref 06223-V3
- Densité/density [2]	1.000 ± 0.030	1.000 ± 0.030 [2]	Internal ref 06224
CONTROLES MICROBIOLOGIQUES / *MICROBIOLOGICAL DATAS*			
- Germes totaux à 30°C : aérobie / *total germs at 30°C : aerobic* [1]	≤ 100 UFC/g	**50 UFC/g**	NF EN ISO 4833-1 – 10/2013
- Levures et moisissures / *yeasts and moulds* [1]	≤ 100 UFC/g	**< 10 UFC/g**	NF V08-036 – 05/2003
- Entérobactéries / *enterobacteria* [1]	Absence/g	**Absence/g**	NF ISO 21528.1 – 12/2014
- Staphylocoques à coagulase + (37°C) dont S.Aureus / *Staphylococci coagulase + (37°C) including S. Aureus* [1]	Absence/g	**Absence/g**	NF EN ISO 6888.3 – 06/2003
- E. Coli / *E. Coli* [1]	Absence/g	**Absence/g**	Internal MA.104.4 adapted from ISO16649.3
- Salmonelle spp/ *Salmonella spp* [1]	Absence/ 10g	**Absence/10 g**	BRD 07/11 - 12/05
- Listeria monocytogenes / *Listeria monocytogenes* [2]	Absence/ 25g	**Absence/25 g** [2]	ALOA-AES 10/3-09/00

STOCKAGE A TEMPERATURE AMBIANTE < 25°C – *STORAGE AT ROOM TEMPERATURE < 25°C*
A CONSERVER DANS SON EMBALLAGE D'ORIGINE - HAS TO BE KEPT IN ITS ORIGINAL PACKAGING

V9–MAJ27052019

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BULLETIN DE CONTROLE
CERTIFICATE OF ANALYSIS
Fabriqué le / *Date of manufacture*: 23/12/2019 – *12/23/2019*
Date de péremption / *Expiry date*: 23/12/2022 – *12/23/2022*

Nom commercial / *Comercial name*: CERAMOSIDES™ OIL NEUTRA
Description du produit / *Product description*: Wheat seed oil
Origine (Genre/Espèce) / *Origin (Genus/Species)*: Blé / *Wheat (Triticum sativum, synonymous vulgare, aestivum)*
Partie de la plante utilisée / *Plant Part Used*: Grain / *Seed*
Lot / *Batch*: 411191223

Contaminants / *Contaminants*

	SPECIFICATIONS *SPECIFICATIONS*	CONTROLE *CONTROL*	METHODES *METHODS*
Métaux lourds / *Heavy metals* [2]			
Plomb / *Lead*	≤ 0.2 ppm	≤ 0.2 ppm [2]	Internal adapted from NF EN 15763
Cadmium / *Cadmium*	≤ 0.1 ppm	≤ 0.1 ppm [2]	
Arsenic / *Arsenic*	≤ 0.1 ppm	≤ 0.1 ppm [2]	
Mercure / *Mercury*	≤ 0.1 ppm	≤ 0.1 ppm [2]	

Allergènes / *Allergens*

	SPECIFICATIONS *SPECIFICATIONS*	CONTROLE *CONTROL*	METHODES *METHODS*
Gluten résiduel / *Residual gluten* [1]	< 20 ppm	< 20 ppm	Internal Ridaquick Gliadine kit (R-Biopharm AG) test
Gluten résiduel / *Residual gluten* [2]	< 20 ppm	< 20 ppm [2]	AOAC-OMA 2012.01

[1] Analyses réalisées sur chaque lot / *testing on each batch*
[2] Analyses garanties sous contrôle statistique : minimum 1 fois par an / *Analysis guaranteed under statistical control : minimum once a year*

Mycotoxines et aflatoxines / *Mycotoxins and aflatoxins :*

Garantie de la matière première selon la règlementation européenne (EC) N°1881/2006 et plan de contrôle sur les CERAMOSIDES™ OIL NEUTRA une fois par an/
Raw material guaranteed with European regulation (EC) N° 1881/2006 and annual control program on CERAMOSIDES™ OIL NEUTRA once a year.

Pesticides / *Pesticides :*

Garantie de la matière première selon la règlementation européenne (EC) N°396/2006 et plan de contrôle sur les CERAMOSIDES™ OIL NEUTRA une fois par an/
Raw material guaranteed under EU regulation (EC) N° 396/2006 and annual control program on CERAMOSIDES™ OIL NEUTRA once a year.

STOCKAGE A TEMPERATURE AMBIANTE < 25°C – *STORAGE AT ROOM TEMPERATURE < 25°C*
A CONSERVER DANS SON EMBALLAGE D'ORIGINE - HAS TO BE KEPT IN ITS ORIGINAL PACKAGING

Approuvé par l'assurance qualité / *Quality assurance approved*

Valérie BIZOT
Ph,D Biochemistry
30/01/2020 – *01/30/2020*

V9–MAJ27052019

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Statement on methods used and correlated versions

NF EN ISO 3960
NF EN ISO 662
NF EN ISO 21528.1

We hereby certify that for the methods NF EN ISO listed above, the last updated versions are used for analysis in the laboratories.

Please find hereafter the method and updated correlated versions:

- NF EN ISO 3960 version 04/2017
- NF EN ISO 662 version 06/2016
- NF EN ISO 21528.1 version 07/2017

The notification of discordance on updated versions used in our COA and Technical data sheets is taken into account and will now be addressed by registration systematically in our software database "Qualishare".

Fait à VILLERS SUR FERE,
Le 20/05/2020

Valérie BIZOT
Quality Manager

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From:	Kayla Preece
To:	Morissette, Rachel
Cc:	West-Barnette, Shayla; Honigfort, Mical; John Endres; Amy Clewell; Jared Brodin
Subject:	FDA GRN 906 and 907-Response to FDA questions
Date:	Tuesday, July 14, 2020 2:03:45 PM
Attachments:	Response to FDA Round II GRN 906 and 907 questions FINAL 2020-07-14 comments.docx

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Hello Dr.Morissette-

We received confirmation from our client sooner than we anticipated and have the responses to the FDA's questions regarding GRNs 906 and 907 now ready. Please find the attachment below. Thank you for your assistance through this process.

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Best regards,
Kayla

Kayla Preece, ND

Scientific and Regulatory Consultant

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Dear Dr. Morissette,
Please find our responses to FDA Round II GRN 906 and 907 questions (2020-06-30) in red below:

In response to Question 2:

- SEPPIC provided references for updated versions of EN ISO 3960-06/2010, NF EN ISO 662-02/2001, and NF ISO 21528.1-12/2014 but not for NF EN ISO 660-09/2009. Please provide a reference for an updated version of NF EN ISO 660-09/2009 or explain why a method that has been withdrawn was used.

Seppic utilizes the NF EN ISO standard listed on the French Agency for Normalization (AFNOR) (https://www.boutique.afnor.org/norme/nf-en-iso-660/corps-gras-d-origines-animale-et-vegetale-determination-de-l-indice-d-acide-et-de-l-acidite/article/687231/fa158625) which has not updated NF EN ISO 660-09/2009 and therefore it remains the utilized method of Seppic.

In response to Questions 7 and 8:

- SEPPIC provided estimates of dietary exposure at the 90th percentile based on lifetime exposure. Please provide estimates at the 90th percentile that are not based on lifetime exposure.

The daily average exposure estimate assessments performed using Creme Global software with regard to the new conditions of intended use are as follows:

For GRN 906, the 90th percentile daily average exposure estimate from use in functional beverages is 39.8 mg/day (0.79 mg/kg bw/day).

For GRN 907, the 90th percentile daily average exposure estimate from use in bars is 100 mg/day (1.7 mg/kg bw/day).

These daily average exposure estimates are greater than the lifetime/usual estimates of 30 mg/day for GRN 906 and 70 mg/day for GRN 907 that were given in the last response to FDA, which is not unusual. However, lifetime/usual exposure estimates are widely accepted, and are considered to represent a more realistic daily intake estimate over the lifetime as opposed to the daily average estimates above.[1-3]

- SEPPIC provided food codes used to estimate dietary exposure to wheat seed powder from its uses in functional beverages. Based on the selected food codes, we assume that the intended use is limited to functional beverages that are fruit/vegetable juice drinks and that are either considered to be energy drinks or contain high levels of added vitamin C. Please confirm that this is a correct assumption. In addition, please clarify if wheat seed oil is intended for use in all bars or in a subset of bars.

The wheat seed oil is intended for use in “functional bars”, and as there are no specific food codes in NHANES data for such bars, all NHANES food codes for bars were used in the exposure estimate assessment in order to get a broad estimate of potential exposure from the ingredient in bars.

The wheat seed powder is intended for use in “functional beverages”, and similarly there are few specific food codes in NHANES data for such beverages. Thus, various beverage codes for drinks that contain a “functional ingredient” (e.g. vitamin C) were chosen for the exposure estimate to represent consumption of this type of beverage. The wheat seed powder will be limited to use in beverages that are generally fruit/vegetable juices, but not specifically to those that contain vitamin C or are considered energy drinks. Again, as there are no current perfect food code choices in NHANES for drinks that contain “wheat seed powder”, the food codes chosen for the estimates merely represent surrogate

beverages that contain functional ingredients, and aren't necessarily considered identical to the functional beverages that wheat seed powder will be added to.

References

1. Hoffmann K, Boeing H, et al. Estimating the distribution of usual dietary intake by short-term measurements. *Eur J Clin Nutr*. 2002;56 Suppl 2:S53-62
2. Food And Nutrition Board and Institute of Medicine. Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. 1997. 1-454.
3. National Center for Health Statistics (NCHS). NHANES Dietary Web Tutorial. Modeling Usual Intake Using Dietary Recall Data. Task 2: Describing Statistical Methods that Have Been Used to Estimate the Distribution of Usual Intake with a Few Days of 24-hour Recalls. Key Concepts about Statistical Methods that have been used to Estimate the Distribution of Usual Intake with a Few Days of 24-hour Recalls. [2011] from https://www.cdc.gov/nchs/tutorials/dietary/Advanced/ModelUsualIntake/Info2.htm.

Two publications have been removed in accordance with copyright laws. The removed reference citations are

S. POTOČKI: Potential health benefits of sphingolipids in milk and dairy products, *Mljekarstvo 66* (4), 251-261 (2016) 251

Sugawara, T., Miyazawa, T. Separation and determination of glycolipids from edible plant sources by high-performance liquid chromatography and evaporative light-scattering detection. *Lipids* **34,** 1231 (1999). https://doi.org/10.1007/s11745-999-0476-3