ORIGINAL SUBMISSION

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#682

November 22, 2016

Dr. Antonia Mattia
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
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: GRAS Notification – Canola Lecithin

Dear Dr. Mattia:

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

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

Sincerely,

(b) (6)

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

GRAS Determination of Canola Lecithin for Use in Food

OCTOBER 26, 2016

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GRAS Determination of Canola Lecithin for Use in Food

SUBMITTED BY:

Cargill, Incorporated
15407 McGinty Road West
Wayzata, MN 55391

SUBMITTED TO:

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

CONTACT FOR TECHNICAL OR OTHER INFORMATION

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Naperville, IL 60565

OCTOBER 26, 2016

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Table of Contents

List of Acronyms

ADME	absorption, distribution, metabolism, and excretion
AGPC	a-glycerylphosphorylcholine
CAS	Chemical Abstract Service
COA	Certificate of Analysis
CFR	Code of Federal Regulations
cGMP	current Good Manufacturing Practices
CIR	Cosmetic Ingredient Review
EFSA	European Food Safety Authority
FCC	Food Chemicals Codex
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food Drug and Cosmetic Act
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
JECFA	Joint FAO/WHO Expert Committee on Food Additives
SCF	European Commission Scientific Committee for Food
SCOGS	Scientific Committee on GRAS Substances
WHO	World Health Organization

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

(1) GRAS Notice Submission

Cargill, Incorporated (Cargill), through its agent, ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the submission of a Generally Recognized as Safe (GRAS) notice for canola lecithin.

(2) Name and Address

Cargill, Incorporated
15407 McGinty Road
Wayzata, MN 55391

(3) Name of Notified Substance

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

(4) Intended Use in Food

Canola lecithin is intended for use as an emulsifier, surfactant, and dispersing agent in foods.

(5) Statutory Basis for GRAS Determination

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

(6) Premarket Approval Statement

Cargill further asserts that the use of canola lecithin in food, including nonexempt infant formula, as described below, is exempt from the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act, based on a conclusion that the notified substance is GRAS under the conditions of its intended use.

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(7) Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent to the FDA on request, or are available for the FDA's review and copying during customary business hours from ToxStrategies, Inc., Naperville, IL.

(8) Data and Information Confidentiality Statement

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

(9) GRAS Notice Certification

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

(10) Name/Position of Notifier

(b) (6)

November 22, 2016

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

Date

(11) FSIS Statement

Not applicable.

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

Identity

The canola lecithin product that is the subject of this GRAS determination is composed of a complex mixture of phospholipids, glycolipids, carbohydrates, and triglycerides. Cargill uses only double zero (00) canola seed to produce canola lecithin. Based on Cargill's liquid canola analyses, the erucic acid content (C22:1) is an average of 0.1%. As such, "canola" in this document refers to low erucic acid rapeseed.

Canola Lecithin (fluid):

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

Canola lecithin is a viscous fluid with a green-brown appearance. It is soluble in hexane, toluene, chlorinated hydrocarbons, in addition to oils and fats.

Canola Lecithin (powder):

Lecithin powder, which typically appears as beige powder, is a mixture of polar (phospho- and glyco-) lipids and a small amount of carbohydrates.

Empirical Formula and Chemical Structure of Lecithin

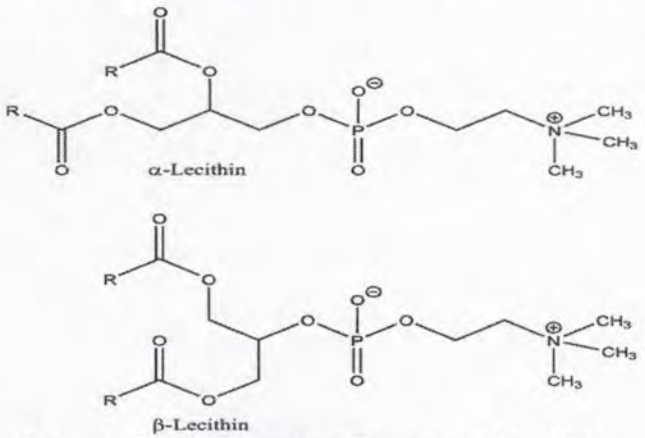

Figure 1: Typical Chemical Structure of Lecithin

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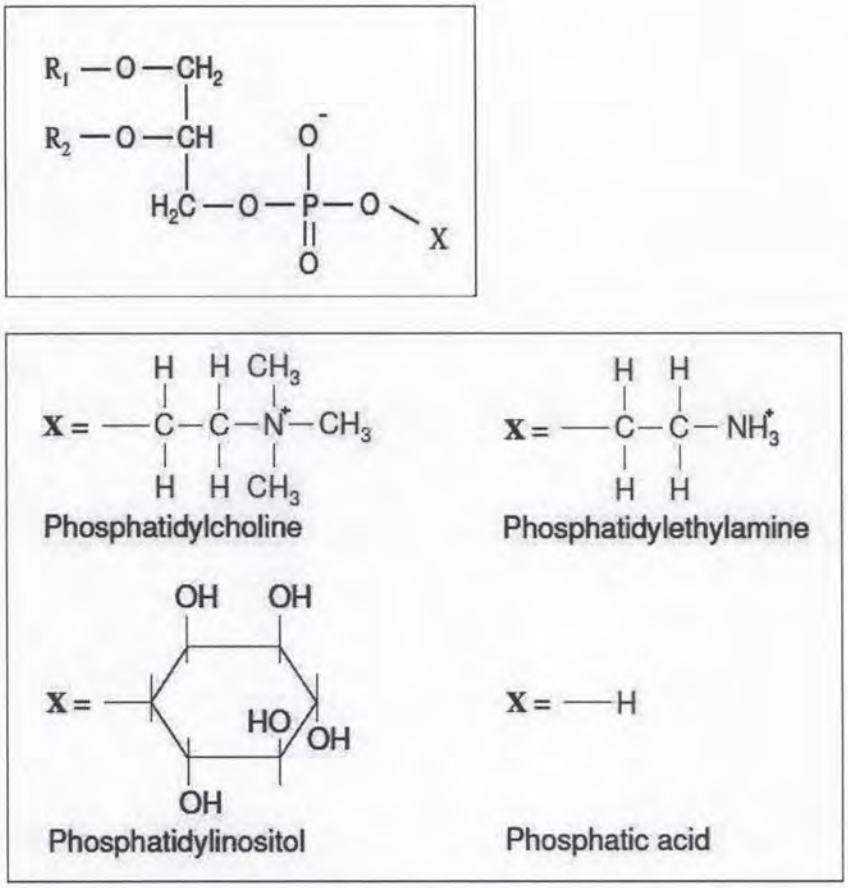

Figure 2: Structure of the main phospholipids of canola lecithin

Common or Chemical Names

The proposed common name for this product is canola lecithin. The CAS number for rapeseed/canola lecithin is 8002-43-5. The trade name of Cargill's canola lecithin product is Lecimulthin RS (powder) or Emulpur RS (powder), and Topcithin RS (fluid).

Manufacturing Process

Cargill's canola lecithin product that is the subject of this GRAS self-determination is derived from crude lecithin that is manufactured according to steps outlined in Figure 3 and that meets specifications set by Cargill to ensure a consistent starting material and to minimize variability of the final lecithin product. Cargill further processes the crude lecithin to produce either a de-oiled canola lecithin (powder) or a standardized canola lecithin (fluid). Both the crude and final lecithin products are manufactured following current Good Manufacturing Practices (cGMP) for food in accordance with Title 21 of the U.S. Code of Federal Regulations (CFR) Parts 110 and 117 Subpart B, utilizing raw

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materials and processing aids that are appropriate for use in foods (Table 1). Flow diagrams (Figures 4 and 5) of Cargill's process precede the narrative description below, which results in a product that complies with Cargill's product specifications for canola lecithin (powder and fluid forms).

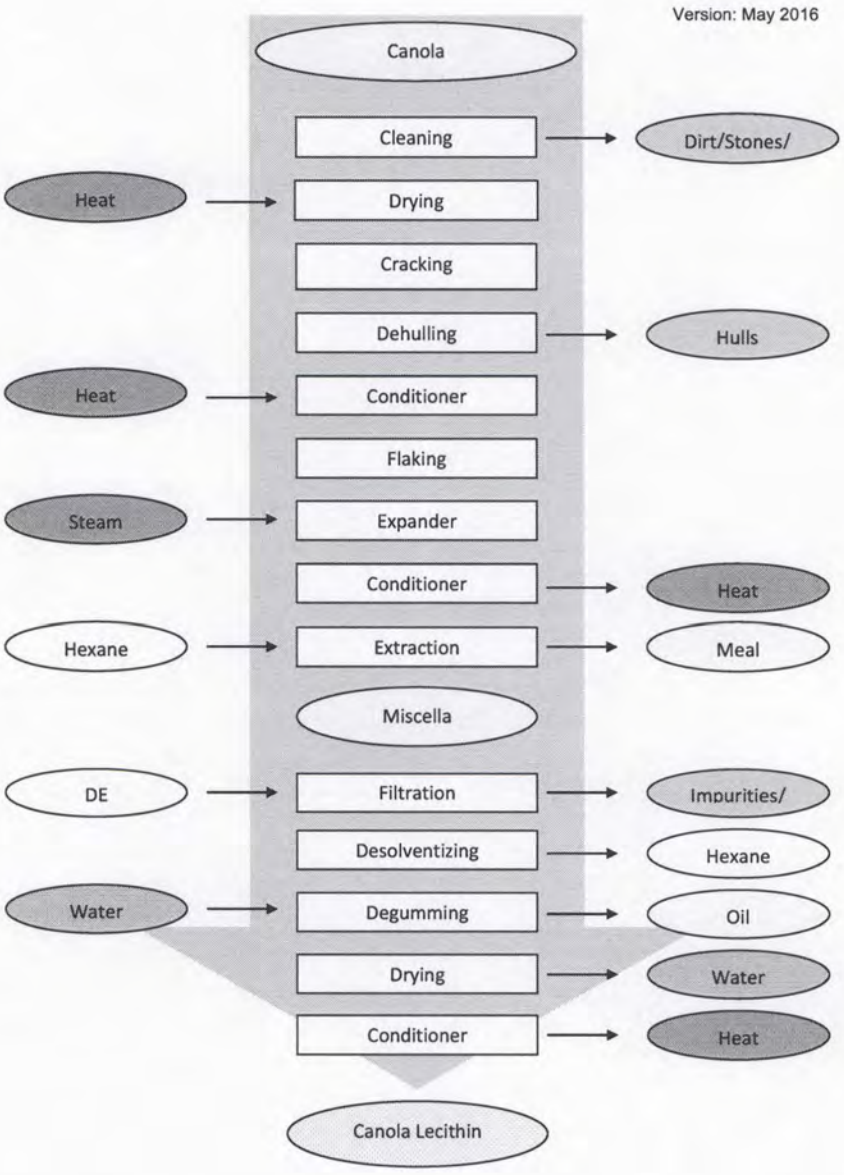

Figure 3. Manufacturing Process Flow Diagram for Crude Canola Lecithin

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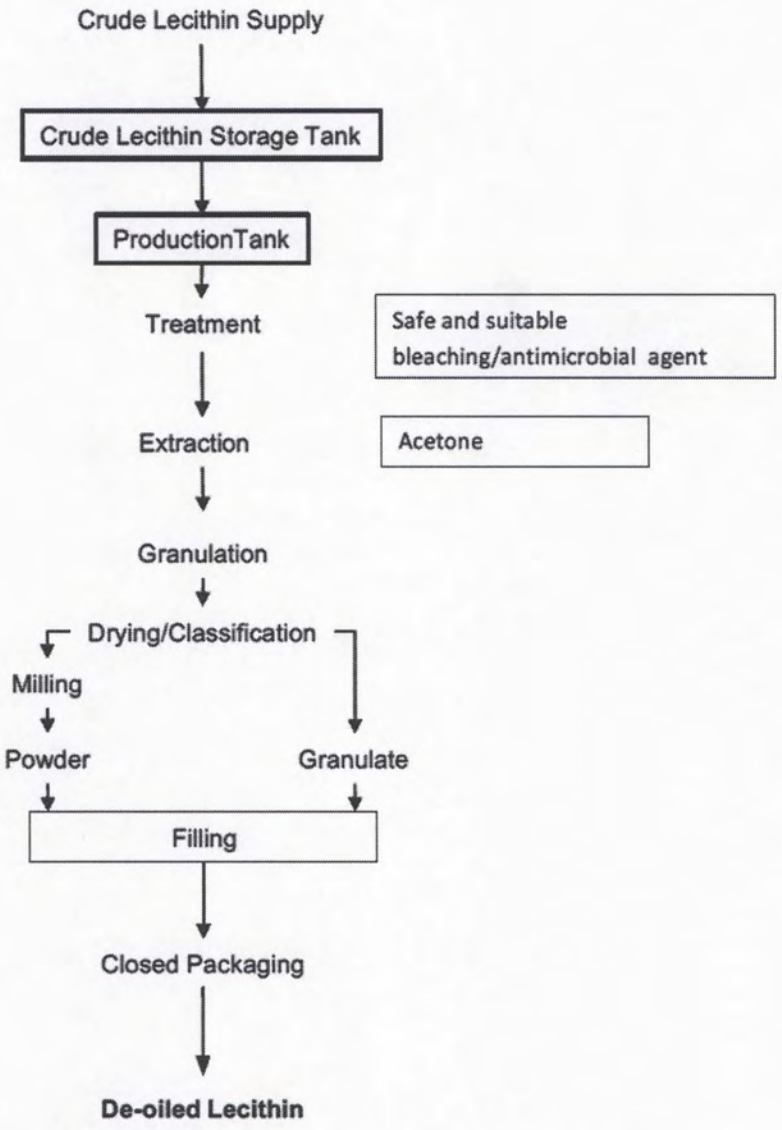

Figure 4. Manufacturing Process Flow Diagram for De-oiled Canola Lecithin

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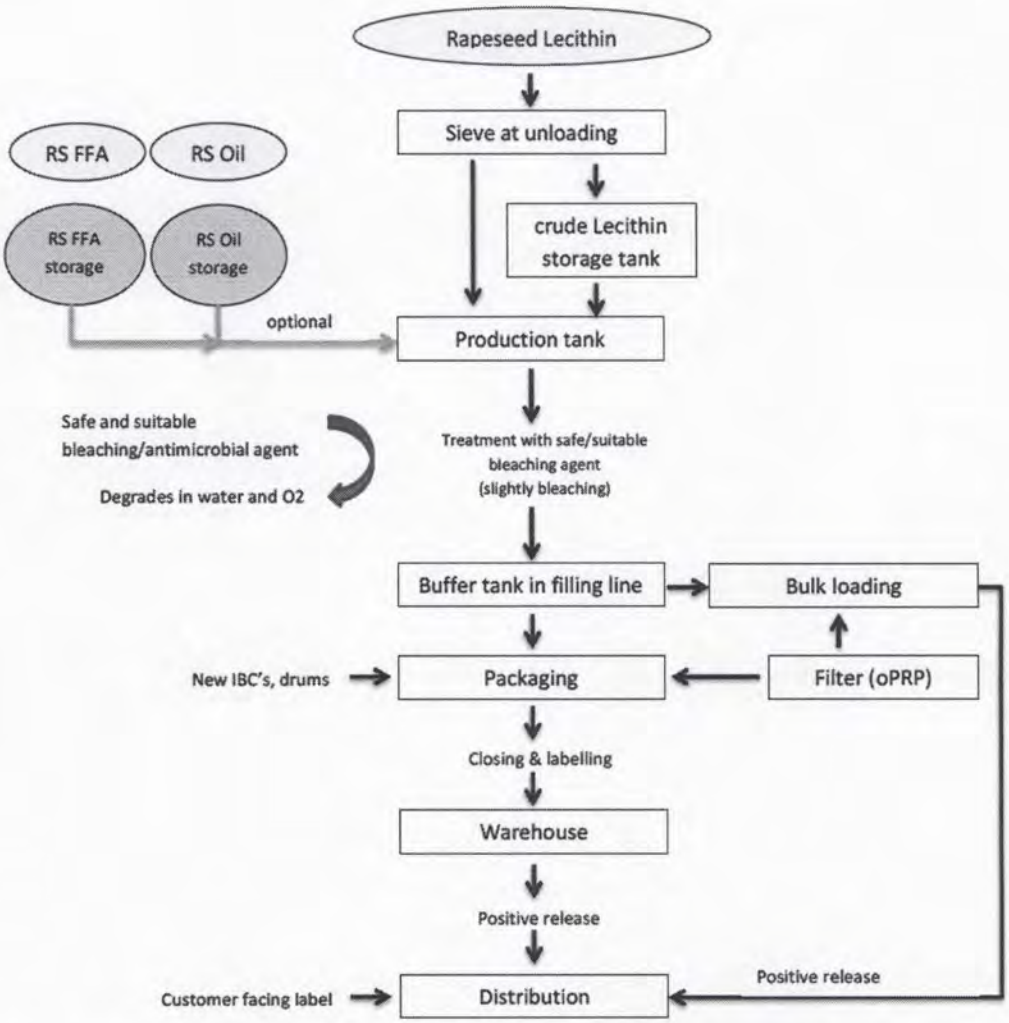

Figure 5. Manufacturing Process Flow Diagram for Standardized Canola Lecithin

Processing of Crude Lecithin

As illustrated in Figure 3, the production of canola lecithin is similar to that of other plant-derived lecithins. The process begins with the conventional preparation of canola through cleaning, drying, tempering, conditioning, flaking, and pressing of the canola seed. Prior to the extraction step, the seed is run through an expander or expeller.

To remove any remaining oil after extraction, the pressed canola seeds (cake) are treated with hexane that is specially refined for the vegetable oil industry. The cake is flooded with solvent or miscella (canola oil plus hexane). Next, the extractor moves the cake and the miscella (solvent plus oil) in opposite directions to create a continuous counter-current extraction.

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A series of pumps spray miscella over the cake, gradually increasing the ratio of solvent to oil. The solvent percolates by gravity through the cake, diffusing into and eventually saturating the cake fragments. After a fresh solvent wash, the hexane-saturated meal leaving the solvent extractor contains less than 1% oil. The most commonly used extractors are baskets with a continuous-loop design.

After extraction, it is common to use miscella filtration, in which the mixture of oil, lecithin, and hexane is run via prefiltration to obtain a size in the range of 50–100 μm, followed by diatomaceous earth (DE) filtration to remove any remaining solid impurities. During the de-solventizing step, the miscella are steam stripped and evaporated from the cake.

The crude canola oil is heated to about 70°C during the degumming process, mixed with 2% water, and then subjected to thorough stirring for about 30 minutes to one hour. The exact temperature, amount of water added, and mixing times vary among the various extraction plants, but all plants produce the ingredient within specifications. The addition of water to the oil hydrates the polar lipids in the oil, making them insoluble and resulting in a lecithin sludge that must be separated by centrifugation. The wet sludge is made up of water, phospholipids, and glycolipids, some triglycerides, carbohydrates, traces of sterols, free fatty acids, and carotenoids.

The crude canola lecithin is then obtained by careful drying using mainly thin-film evaporators to dry the gums. After drying, the crude lecithin can by altered by addition of canola oil or/and canola fatty acid to meet the specified canola lecithin quality.

De-Oiling with Acetone to Manufacture Powdered Lecithin

Crude lecithin contains about 30%–40% neutral lipids, mainly triglycerides. To improve the processing characteristics and dispersant properties of high-viscosity crude lecithin, acetone extraction is performed to remove neutral lipids, mainly triglycerides, and obtain polar lipids, such as phospholipids and glycolipids. By utilizing an extraction with acetone (Figure 4), a de-oiled lecithin with a residual content of only 2%–3% neutral lipids is produced. The resulting products can be made into powder or granulated forms and display a significant improvement in emulsifying capacity and in dispersibility in water. The key element of the de-oiling process is that the phospholipids, as the components that provide functionality, have now been concentrated and purified. This results in significantly lower use level requirements and higher functionality. In addition, the de-oiled products have a more neutral taste than the corresponding liquid products, because most of the aroma components are removed with the acetone.

Standardization

The composition of lecithins may vary considerably depending on the raw material source. Even more specifically for canola lecithin, the canola variety, the geographic region, weather, storage, and processing conditions can have a significant influence on the various quality aspects of lecithins produced.

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The various constituents of lecithins (phospholipids) contribute in different ways to the functionality of lecithin in the final application; therefore, it is reasonable to standardize the final lecithin products in order to guarantee a consistent composition, and thereby its functionality. Also the total phospholipid contents may vary significantly and may need to be adjusted.

Reagents/processing aids used in the manufacture of canola lecithin are listed in Table 1 below, and all are commonly used in food additive/ingredient manufacturing processes.

Table 1. Reagents/Processing Aids — Canola Lecithin

Reagent/Processing Aid	CAS Number	21 CFR Citation(s)
Acetone	67-64-1	21 CFR §173.210
Hexane	7732-18-5	21 CFR §173.270
Nitrogen	7727-37-9	21 CFR §184.1540

Product Specifications

The proposed food-grade specifications for Cargill's canola lecithin product are presented in Table 2, along with a comparison to the specifications published in the Food Chemicals Codex (FCC) 10th Edition. The specifications established for Cargill's canola lecithin product meet or exceed the published FCC specifications.

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Table 2. Proposed Specifications for Canola Lecithin and Comparison to FCC Specifications

Parameter	FCC Specification for Lecithin	Cargill's Canola Lecithin Specification
Chemical and Physical Specifications		
Acetone-Insoluble Matter (%)	NLT 50	NLT 60 (fluid); NLT 96 (powder)
Hexane/Toluene-Insoluble Matter* (%)	NMT 0.3	NMT 0.3
Acid Value (mg KOH/g)	NMT 36	NMT 35
Peroxide Value (meq O_2/kg)	NMT 100	NMT 5
Moisture/Loss on Drying (%) (105°C, 1hr)	NMT 1.5	NMT 1.5 (powder); NMT 1.5 (fluid)
Lead (ppm)	NMT 1	NMT 1 (powder); NMT 1 (fluid)
Microbiological Specifications		
Total Plate Count (cfu/g)	--	NMT 1,000
Yeast (cfu/g)	--	NMT 50
Mold (cfu/g)	--	NMT 50
Enterobacteriaceace (/g)	--	Absent
Salmonella (/375g)	--	Absent

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

Analytical results for additional select nutritional parameters and potential contaminants are provided in Tables 3 and 4. As stated in the identity section, canola lecithin consists of phosphatidylcholine, phosphatidylethanolamine, phosphatidylinositols, and phosphatidic acids, which according to Table 4, represent 40% and 67% of the fluid and powder canola lecithin's composition, respectively. Results of these additional analyses are included in the certificates of analysis (COAs) found in Appendix A.

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Table 3. Typical Fatty Acid Analysis for Canola Lecithin (fluid and powder forms)

Fatty Acid	Canola Lecithin
Palmitic (C16:0)	8%
Stearic (C18:0)	1%
Oleic (C18:1)	55%
Linoleic (C18:2)	27%
Linolenic (C18:3)	7%
Others	2%
Total	***100%***

Table. 4 Typical Phospholipid Composition of Canola Lecithin (fluid and powder forms, n=6)

Phospholipids	Fluid Canola Lecithin	Deoiled Canola Lecithin (Powder)
Phosphatidylcholine (PC)	17%	28%
Phosphatidylethanolamine (PE)	9%	17%
Phosphatidylinositols (PI)	11%	18%
Phosphatidic Acids (PA)	3%	4%

Comparisons of three non-consecutive lots of both the fluid and powder forms of Cargill's canola lecithin to the proposed specifications are provided in Tables 5 and 6. The difference between the fluid and powder forms of canola lecithin is mainly the specifications and analysis of the total phospholipid content reported as acetone insolubles. As illustrated in Tables 5 and 6, the canola lecithin consistently meets specifications, indicating a well-controlled, consistently manufactured product. All of Cargill's lecithin is manufactured according to cGMP, as defined in 21 CFR § 110 and § 117 Subpart B.

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Table 5. Analytical Data for Three Non-Consecutive Lots of Canola Lecithin Fluid

Parameter		Lecithin (fluid)		
	Cargill Specifications for Lecithin	**10316HSDBA**	**PPD2016-036**	**917-488-5**
Chemical and Physical Specifications				
Acetone Insolubles (%)	NLT 60	61.5	61	62
Hexane Insoluble Matter (%)	NMT 0.3	0.06	0.01	0.04
Toluene Insoluble Matter (%)	NMT 0.3	0.05	0.08	0
Moisture (%)	NMT 1.5	0.25	0.18	0.38
Peroxide Value (meq/kg)	NMT 5	<1	<1	<1
Acid Value (mg KOH/g)	NMT 35	17.2	17.4	16.6
Lead* ppm	NMT 1	<0.05	<0.5	<0.05
Microbiological Specification				
Total plate count (cfu/g)	NMT 1000	<100	<100	<40
Yeasts (cfu/g)	NMT 50	Negative	Negative	<10
Molds (cfu/g)	NMT 50	Negative	Negative	<20
Enterobacteriaceae (/g)	Absent	Absent	Absent	Absent
Salmonella (/375g)	Absent	Absent	Absent	Absent

* Based on analysis of crude lecithin (raw material)

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Table 6. Analytical Data for Three Non-Consecutive Lots of Canola Lecithin Powder

Parameter		Lecithin (powder)		
	Cargill Specification for Lecithin	863007	102493	863016
Chemical and Physical Specifications				
Acetone Insolubles (%)	NLT 96	98.7	97.3	97.7
Hexane Insoluble Matter (%)	NMT 0.3	0.07	0.05	0.02
Toluene Insoluble Matter (%)	NMT 0.3	0.07	0.05	0.04
Moisture (%)	NMT 1.5	0.3	0.95	0.55
Peroxide Value (meq/kg)	NMT 5	<1	<1	<1
Acid Value (mg KOH/g)	NMT 35	23.1	23.5	23.2
Lead* ppm	NMT 1	<0.5	<0.05	0.05
Microbiological Specification				
Total plate count (cfu/g)	NMT 1000	10	100	100
Yeasts (cfu/g)	NMT 50	Negative	Negative	Negative
Molds (cfu/g)	NMT 50	Negative	Negative	Negative
Enterobacteriaceae (/g)	Absent	Absent	Absent	Absent
Salmonella (/375g)	Absent	Absent	Absent	Absent

* Based on analysis of crude lecithin (raw material). Testing reveals no enrichment during the deoiling process; hence, no change expected in heavy metal content from lecithin production process.

In summary, the analytical (physical, chemical, and microbiological) results for canola lecithin summarized in the above tables and included in the COAs in Appendix A confirm that the finished product meets the proposed analytical specifications and demonstrates the consistency of production. The analytical results also confirm the lack of impurities/contaminants (e.g., heavy metals, pesticides, mycotoxins). Further, the data provided from the analyses of the three non-consecutive lots consistently demonstrates that the specifications established for Cargill's canola lecithin product meet or exceed the published FCC specifications.

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Stability Data

The above canola lecithin product meets Cargill's proposed analytical specifications. Similar to other Cargill plant-based lecithin ingredients, the recommended shelf life for both the fluid and powder forms of canola lecithin is a minimum of 12 months. Stability testing of the proposed canola lecithin ingredient is ongoing. The recommended storage conditions are to reclose packaging immediately after opening. Store in a dry place between 15 and 30°C (59 to 86°F) for fluid lecithin and <25°C (<77°F) for de-oiled lecithin, and store in its original packaging until used.

§ 170.235 Part 3, Dietary Exposure

Canola lecithin is intended for addition to foods as a nutritional ingredient and as an emulsifier; wetting or instantizing agent; viscosity modifier; releasing agent; extrusion aid; low-flavor binding material; and high-quality dietary fat source. According to 21 CFR § 184.1400, lecithin that is solvent-extracted from soy, safflower, or corn oils can be used without limitation other than cGMPs. Cargill's canola lecithin is intended for use as an alternative lecithin source to lecithins derived from other plant sources and will be employed in a similar fashion.

Cargill's canola lecithin product is intended for use as an alternative source of lecithin in all currently approved food categories (including as an emulsifying agent in meat and poultry; 9 CFR § 424.1) in accordance with cGMP. As described in numerous GRAS Notifications, including GRN No. 533 for canola lecithin, the typical uses of lecithin in foods include but are not limited to baked goods, dairy products, milk analog beverages, breakfast cereals, pasta, confections, soups, stews, chili, ice cream/frozen desserts, margarines/spreads, ovenable breadings and coatings, frostings, non-dairy creamer, sauces/gravies, and as a dietary source of choline in milk-based non-exempt infant formula for term infants at levels up to 3 grams (g) per 100 g. GRN 533 estimated the average dietary exposure to canola lecithin from the intended food uses and use levels to be 6.8-9.5 g per person per day (i.e., equivalent to 113-160 mg/kg bw/day for a 60 kg adult and 226-320 mg/kg bw/day for a 30 kg child).

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

§ 170.240 Part 4, Self-Limiting Levels of Use

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

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

While plant-based lecithin ingredients including canola have been commonly used in food, the statutory basis for our conclusion of GRAS status in the notice is based on scientific procedures and not common use in food.

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§ 170.250 Part 6, GRAS Narrative

History of Use and Regulatory Approval of Canola Lecithin

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

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

Lecithin was discovered in 1846, and industrial production began in the 1920s when an extraction process from plant sources was implemented.

Numerous lecithin ingredients from other plant or grain sources are recognized as GRAS for their intended uses in foods, and the lecithin ingredients listed in Table 7 have received "no questions" letters from the Food and Drug Administration (FDA).

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Table 7. Lecithin GRAS Notifications

GRN No.	Lecithin Product	Date of Closure
637	Phosphatidylserine derived from soy lecithin	Pending
534	Hydrogenated lecithin from soy	12/22/14
533	Lecithin from canola	03/20/15
226	Lecithin derived from krill	01/03/08
186	Soy lecithin enzymatically modified to contain increased phosphatidylserine	07/20/06
134	Soy protein hydrolysate with enzyme-modified lecithin	01/08/04

Safety

Introduction

Lecithin is a direct food substance affirmed as GRAS in 21 CFR § 184.1400, which states that "commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of othe[r] lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils." According to 21 CFR § 184.1400, lecithin from soy, safflower, or corn oils can be used in food with no limitation other than cGMP. Canola oil is proposed as an alternative source of lecithin, and the canola lecithin that is the subject of the GRAS determination would be added to food in a manner similar to the oil sources cited in 21 CFR § 184.1400. The identity of the Cargill canola-derived lecithin is nearly identical to the product considered GRAS in GRN 533 (FDA, 2014b), which received no questions from FDA, and is proposed for the same intended uses therein.

Enzyme-modified lecithin is also GRAS according to 21 CFR § 184.1063. Other sources for or derivatives of lecithin that have been notified as GRAS to FDA with "no questions" letters issued include krill-based (GRN 226; FDA, 2007)), soy lecithin phosphatidylserine complex (GRN 186; FDA, 2005), phosphatidylserine derived from sunflower lecithin or soy lecithin (GRN 545; FDA, 2014d), and soybean-derived hydrogenated lecithin (GRN 534; FDA, 2014c). In addition, lecithin is approved in 9 CFR § 424.21 for use as an emulsifying agent and antioxidant in oleomargarine, shortening, and various meat and poultry products.

Safety Data

The Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974) evaluated lecithin in 1974 and concluded the acceptable daily intake to be "not limited." The European Commission Scientific Committee for Food (SCF) previously determined

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lecithins to be safe for use in foods and infant formula (SCF 1982, 1997). The European Food Safety Authority (EFSA) in 2015 issued a call for data on lecithins for a re-evaluation of use as additives to human foods (http://www.efsa.europa.eu/en/data/call/150608); no updated opinion based on any reevaluation has been published to date. However, EFSA issued a Scientific Opinion on the safety and efficacy of lecithins for feed for all animal species, which concluded "the use of lecithins in animal nutrition does not pose any risk to the consumer" (EFSA, 2016). Finally, the Cosmetic Ingredient Review Panel (CIR, 2015) evaluated lecithins as a class (including 17 phosphoglycerides) and concluded them to be "safe in the present practices of use and concentration in cosmetics, as described in this safety assessment"; use concentrations were reported to be up to 50% in leave-on products.

As noted above, the identity and composition of the Cargill canola lecithin is almost identical to that of other approved lecithin products and consistent with Food Chemicals Codex specifications (10^{th} edition). It is also derived from low erucic acid canola seed and therefore has a low erucic acid content. Tables 8 and 9 summarize the phospholipid and fatty acid profiles of canola-derived lecithin and other approved lecithins included in the CFR or with GRNs. As fatty acids and phospholipids are common dietary components and constituents of cell membranes, minor differences in relative amounts present in lecithin products are of no safety concern in regard to the proposed canola lecithin product and its use in food. Generally, the difference in the fatty acid profile is the slightly higher concentration of mono-unsaturated oleic acid and lower concentration of di-unsaturated linoleic acid in the canola products. This variation in the oleic:linoleic ratio was acknowledged in GRN 533 and considered to be GRAS with a "no questions" letter received from FDA. Of note, a range of products and associated compositions were included in GRN 533, including a purified phosphatidylcholine product with 61.1% oleic acid, which is more than the oleic acid content of the Cargill product (range 55.3%–56.6%). In addition, high-oleic-acid cooking oils are part of the common diet (olive oil, canola oil-GRAS in 21 CFR § 184.1555), and related products have been notified as GRAS with "no questions" letters received from FDA; these include low-saturated, high-oleic, low-linolenic soybean oil (GRN 306-55%–85%; FDA, 2009) and of high-oleic *Prototheca moriformis* S2532 algal oil (GRN 527-86%–89%; FDA, 2014a). GRN 305 provides a comprehensive overview of the available human epidemiological and clinical data on the intake of oleic acid, concluding that no adverse outcomes were associated with higher intakes.

The safety of lecithins has been evaluated, and they have been deemed safe for human consumption by various organizations, as discussed above. It is important to note that the data used to support a safety conclusion in each of these evaluations varied widely. This variable approach is due to the composition and nature of lecithins. Given that lecithin is a mixture consisting of phospholipids (primarily phosphatidylcholine, phosphatidylethanolamine, phosphatidic acid, and phosphatidylinositol), fatty acids, and other minor components (e.g., triglycerides and carbohydrates), it is reasonable that an evaluation of any of these constituents is pertinent to a safety determination.

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For example, JECFA (1974) included only a few studies of egg yolk phosphatides in animals and on lecithin administration in humans, concluding, "Although fewer toxicological studies have been conducted than would normally be required for substances used as food additives, it is considered that nutritional and clinical experience with lecithin is sufficiently extensive to compensate for the incompleteness of the experimental data." In 1979, the Select Committee on GRAS Substances (SCOGS) issued an opinion on lecithin, hydrogen peroxide bleached, and lecithin, based on a 2-year feeding study of lecithin in rats (Brantom et al., 1973) and exposures in humans. SCF (1982) similarly included a few studies on lecithin administration in rats. The EFSA Scientific Opinion on the safety and efficacy of lecithins for all animal species relied entirely on the data reported by CIR (2015; discussed below) and one other study on phospholipids, and concluded that "[t]he toxicological data on lecithins showed no effects of concern and no indication of genotoxicity and carcinogenicity." The CIR Panel (2015) provided a comprehensive review of the available toxicokinetic and toxicological literature on lecithins and other phosphoglycerides in reaching its conclusion: these included lecithin, lysolecithin, lysohosphatidic acid, phosphatidylserine, phosphatidylcholine, phosphatidylethanalomine, phosphatidylinositol, hydrogenated lecithin, and phosphatidic acid.

Given the extensive reviews already performed and available, the safety sections of more recent GRNs have been limited in the additional safety data provided. For example, GRNs 533 and 534 reviewed only more recent data on the phosphatidylcholine degradation product, a-glycerylphosphorylcholine (AGPC); this GRN included acute, subchronic, and genetic toxicity. In the case of GRN 226 (FDA, 2007), the safety section addressed only potential differences in marine-derived phosphatidylcholine and associated lipids (focused on DHA and EPA) versus other approved phospholipids. No toxicological or additional safety data were discussed beyond the basic biochemistry of lecithin in the human body; the GRN noted that "the constituents of krill-based lecithin are commonly found in food" and did not discuss it further.

As described by Grundy (1987) and reviewed in GRNs 226 and 533 and EFSA (2016), dietary lecithin is generally absorbed in humans, with the majority being incorporated into the surface coat of chylomicrons. On ingestion, a small amount of lecithin is absorbed intact in the small intestines (primarily the duodenum and upper jejunum). The remaining majority of lecithin undergoes hydrolysis by pancreatic phospholipase A2, and the resulting lysolecithins and fatty acids are taken up by mucosal cells. Once taken up by mucosal cells, lysolecithin has been shown to undergo different processes: (1) re-esterification with a fatty acid (the resulting lecithin can be used in normal biological functions, such as becoming part of cell membranes or coating chylomicrons), (2) complete lipolysis (the released fatty acids can become triglycerides), or (3) absorption into portal circulation (Grundy, 1987).

Based on the biochemistry and fate of lecithins in the human body, lecithin derived from an alternative source, such as canola oil, would not be expected to have different toxicokinetic properties than other, plant-derived lecithins that have already been determined to be GRAS for human consumption. The safety reviews described above-

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CFR, SCOGS, SCF, GRNs, CIR, and EFSA—each involved a panel of qualified experts charged with reaching a conclusion regarding the safe use of a lecithin-related product for human use. These evaluations cover all toxicological endpoints relevant to the human oral consumption of lecithin (e.g., absorption, distribution, metabolism, and excretion [ADME], acute and repeated-dose oral toxicity, reproductive and developmental toxicity, genotoxicity, mutagenicity, carcinogenicity, and sensitization/allergenicity), and therefore, it can be considered that the totality of information available on lecithin and related compounds is sufficient to support the safe use of lecithin derived from canola oil for the proposed intended uses described herein.

It should be noted that a CIR panel (2015) raised a question concerning possible nitrosamine formation from the use of lecithin ingredients. The Expert Panel has considered the CIR report and concludes that the conditions under which nitrosamine formation could potentially occur are not consistent with food production or storage of food and are therefore not a concern in this assessment. Furthermore, the Expert Panel does not believe a cautionary statement for nitrosamines is required or that any concern about nitrosamines is warranted for this ingredient.

In addition to an extensive search of regulatory agency databases such as FDA and EFSA, a targeted search was also performed to identify relevant information in monographs and other documents known to evaluate constituents of plant-derived materials, such as the European Medicines Agency monographs, WHO Monographs on Selected Medicinal Plants, European Scientific Cooperative on Phytotherapy monographs, and the German Commission E monographs; no additional information was found. Comprehensive searches performed using the PubMed and Embase databases returned approximately 2,000 studies. However, our review of these titles revealed no new safety data pertinent to this evaluation. A more detailed review of studies published more recently was also performed (limited to studies published in 2015–2016, the period of time since FDA's review of GRN 533) and no additional data relevant to the safety of canola lecithin in food were identified.

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Table 8. Main Phospholipid Profile of Canola Lecithin Product Compared to Other Sources of Lecithin Confirmed as GRAS

Phospholipid	Percent of Phospholipids (w/w%)					
	Cargill Canola Lecithin Product[A]	**Canola Lecithin[B]**	**Soy Lecithin[C]**	**Krill Lecithin[D]**	**Corn Lecithin[E]**	**Sunflower Lecithin[F]**
Phosphatidylcholine	15-19	13-25	13-38	46-95	31	14-30
Phosphatidylethanolamine	7-9	6-14	8-23	36-85	3	7-24
Phosphatidylinositol	10-12	8-14	10-21	0-7	16	13-17
Phosphatidic Acid	2-3	1-7	2-16	NR	9	1-7

[A]Values for canola lecithin product represent the range of seven samples from different sources.

[B]Cargill internal data; GRN 533 crude canola lecithin product.

[C]Cargill internal data; Schofield, 1981; van Nieuwenhuyzen, 2014; Szuhaj, 1987

[D]GRN 226

[E]Szuhaj, 1987

[F]Cargill internal data; van Nieuwenhuyzen, 2014

NR - not reported

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Table 9. Main Fatty-Acid Profile of Canola Lecithin Product Compared to Other Sources of Lecithin Confirmed as GRAS

Fatty Acid	Percent of Total Fatty Acids (w/w%)					
	Cargill Canola Lecithin Product[A]	**Canola Lecithin[B]**	**Soy Lecithin[C]**	**Krill Lecithin[D]**	**Corn Lecithin[E]**	**Sunflower Lecithin[F]**
Palmitic (C16:0)	8	7-10	11-20	13-15	18	8-14
Stearic (C18:0)	1	1-3	3-6	0.7-0.9	2	2-7
Oleic (C18:1)	53-57	52-57	9-24	6-13	25	6-40
Linoleic (C18:2)	25-28	25-29	50-60	2	54	42-68
Linolenic (C18:3)	7-8	6-8	5-9	NR[F]	1	0-1

[A]Values for canola lecithin product represent the range of six samples from different sources.

[B]Cargill internal data; GRN 533 crude canola lecithin product.

[C]Cargill internal data; van Nieuwenhuyzen, 2014; Szuhaj, 1987

[D]GRN 226

[E]Szuhaj, 1987

[F]Cargill internal data; van Nieuwenhuyzen, 2014

[G]Source did not provide a value for this fatty acid in the table— unclear whether it was not evaluated or if it was below the limit of detection/quantification.

NR - not reported

Safety Data Summary

In summary, the safety of canola lecithin for the proposed uses in food has been demonstrated sufficiently in multiple previous evaluations conducted by qualified experts. The composition of the proposed canola lecithin product is nearly identical to other GRAS-notified lecithin ingredients derived from other plant sources. The constituents of canola lecithin are commonly consumed as part of a normal human diet. No relevant data published since 2015 were identified; however, the totality of information reviewed in already existing evaluations is sufficient to support the safe use of canola lecithin for the intended uses.

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Basis for the GRAS Determination

Introduction

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

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

These criteria are applied in the analysis below to determine whether the use of canola lecithin in food for human consumption is GRAS based on scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FFDCA.

Safety Determination

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

The identity of the Cargill canola-derived lecithin is nearly identical to the product considered GRAS in GRN 533 (FDA, 2014b), which received no questions from FDA, and is proposed for the same intended uses therein. Enzyme-modified lecithin is also GRAS according to 21 CFR § 184.1063. Other sources for or derivatives of lecithin that have been notified as GRAS to FDA with "no questions" letters issued include krill-

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based (GRN 226; FDA, 2007), soy lecithin phosphatidylserine complex (GRN 186; FDA, 2005), phosphatidylserine derived from sunflower lecithin or soy lecithin (GRN 545; FDA, 2014d), and soybean-derived hydrogenated lecithin (GRN 534; FDA, 2014c). While the phospholipid profiles and fatty acid composition of these other GRAS lecithins can vary, phospholipids and lipids are considered safe as they are commonly found in foods and are constituents of human cells. As such, they would be expected to be handled metabolically in a similar way as endogenous materials or those consumed from other foods in the diet.

Based on the biochemistry and fate of lecithins in the human body, it is not expected that lecithin derived from an alternative source such as canola oil would have toxicokinetic properties different from other plant-derived lecithins that have already been determined to be GRAS for human consumption. The safety reviews described above - by FDA in the CFR, SCOGS, SCF, GRNs, CIR, and EFSA—each involved a panel of qualified experts charged with reaching a conclusion regarding the safe use of a lecithin-related product for human use. These evaluations covered all toxicological endpoints relevant to human oral consumption of lecithin (e.g., ADME, acute and repeated-dose oral toxicity, reproductive and developmental toxicity, genotoxicity, mutagenicity, carcinogenicity, and sensitization/allergenicity).

Regulatory authorities have reviewed the composition and safety study database for various plant-derived lecithin products, including canola lecithin, and found no issues of concern with respect to their use in human food, including non-exempt infant formula. Therefore, it can be considered that the totality of information available on lecithin and related compounds is sufficient to support the safe use of the proposed lecithin derived from canola oil for the intended uses herein.

General Recognition of the Safety of Canola Lecithin

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

- The lecithin that is the subject of this notification is a mixture of acetone-insoluble phosphatides that consists mainly of phosphatidylcholine, phosphatidylethanolamine, phosphatidylinositol, and phosphatidic acid, as well as diverse amounts of other substances such as triglycerides, fatty acids, and carbohydrates derived from canola. The canola lecithin product is manufactured consistent with cGMP for food (21 CFR § 110 and § 117 Subpart B). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use as in food.

- The long history of lecithin consumption by humans is common knowledge. Numerous food products containing canola-derived lecithin and/or lecithin derived from other plant sources are marketed in the U.S. and around the world. Lecithin has become a desirable ingredient for addition to a variety of food

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products as a nutritional ingredient and as an emulsifier, wetting or instantizing agent, viscosity modifier, releasing agent, extrusion aid, low-flavor binding material, and high-quality dietary fat source.

- Lecithin is approved for use in food in 21 CFR § 184.1400 and it can be used in food with no limitation other than cGMP. Cargill's canola lecithin is intended for use as a source of lecithin that is an alternative to lecithins derived from other plant sources such as soy, corn, and sunflower. Numerous lecithin ingredients from other plant or grain sources are recognized as GRAS for their intended uses in foods, including lecithin from canola, lecithin from krill, hydrogenated lecithin from soy, phosphatidylserine derived from soy lecithin, soy lecithin enzymatically modified to contain increased phosphatidylserine, and soy protein hydrolysate with enzyme-modified lecithin.

- Based on the biochemistry and fate of lecithins in the human body, it is not expected that lecithin derived from an alternative source such as canola oil would have toxicokinetic properties different from other, plant-derived lecithins already determined to be GRAS for human consumption. Safety reviews by SCOGS, SCF, GRNs, CIR, and EFSA each involved a panel of qualified experts charged with reaching a conclusion regarding the safe use of a lecithin-related product for human use. The evaluations covered all toxicological endpoints relevant to human oral consumption of lecithin (e.g., ADME, acute and repeated-dose oral toxicity, reproductive and developmental toxicity, genotoxicity, mutagenicity, carcinogenicity, and sensitization/allergenicity).

- Regulatory authorities have reviewed studies on the composition and safety of various plant-derived lecithin products, including canola lecithin, and found no issues of concern with respect to their use in human food, including non-exempt infant formula.

- Therefore, the publicly available scientific literature on the consumption and safety of canola lecithin and lecithin ingredients is sufficient and supports the safety and GRAS status of the proposed canola lecithin product.

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

Determination of the safety and GRAS status of canola lecithin that is the subject of this self-determination has been made through the deliberations of an Expert Panel convened by Cargill that comprised Michael Carakostas, DVM, Ph.D.; Stanley M. Tarka, Jr., Ph.D., F.A.T.S.; and Thomas Vollmuth, Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that canola lecithin, produced consistent with GMP and

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meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concludes that these uses of canola lecithin are GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions. The Panel's GRAS opinion is included in this document as Exhibit 1.

It is also Cargill's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Cargill has concluded that canola lecithin is GRAS under the intended conditions of use, on the basis of scientific procedures; therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Cargill is not aware of any information that would be inconsistent with a finding that the proposed use of canola lecithin in food for human consumption that meets appropriate specifications, and used according to GMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

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§ 170.250 Part 7, Supporting Data and Information

The following references are all generally available, unless otherwise noted. Appendix A and Exhibit 1 (analytical COAs for canola lecithin, signed Expert Panel report) are not generally available but are attached for reference.

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APPENDIX A

Certificates of Analysis

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Certificate of Analysis

Product: **DP 1050**
Batch: 10316HSDBA
Manufacturing date: **04/ 2016**
Best before: **04/ 2017**

Parameter	Method	Actual Value
Aceton Insolubles	AM-22	61,5 %
Toluene Insolubles	AM-30	0,05 %
Hexane Insolubles	AM-36	0,06 %
Moisture	AM-30	0,25 %
Peroxide value	AM-24	<1 meq / kg
Acid value	AM-28	17,2 mg KOH/ g
Iodine colour value	AM-25	65
Total Plate Count	MB 2.1	<100 / g
Yeast	MB 3.1	negative / g
Mould	MB 3.1	negative / g
Enterobacteriaceae	MB 4.2.1 + MB 4.3 or Enterotube	negative / g
Salmonella	RT-PCR	negative / 375 g

Hamburg, 4. Oktober 2016

computer/electronically printed and therefore no signature

Certificate of Analysis

Product: **Rapseed lecithin fluid**
Batch: PPD2016-036
Manufacturing date: **02/ 2016**
Best before: **02/ 2017**

Parameter	Method	Actual Value
Aceton Insolubles	AM-22	61 %
Toluene Insolubles	AM-30	0,08 %
Hexane Insolubles	AM-36	0,01 %
Moisture	AM-30	0,18 %
Peroxide value	AM-24	<1 meq / kg
Acid value	AM-28	17,42mg KOH/ g
Iodine colour value	AM-25	63,3
Total Plate Count	MB 2.1	<100 / g
Yeast	MB 3.1	negative / g
Mould	MB 3.1	negative / g
Enterobacteriaceae	MB 4.2.1 + MB 4.3 or Enterotube	negative / g
Salmonella	RT-PCR	negative / 50g

Hamburg, 4. Oktober 2016

computer/electronically printed and therefore no signature

Certificate of Analysis

Product: **Rapseed lecithin fluid**
Batch: 917488-5
Manufacturing date: **05/ 2016**
Best before: **05/ 2017**

Parameter	Method	Actual Value
Aceton Insolubles	AM-22	62 %
Toluene Insolubles	AM-30	0,0 %
Hexane Insolubles	AM-36	0,04 %
Moisture	AM-30	0,38 %
Peroxide value	AM-24	<1 meq / kg
Acid value	AM-28	16,6mg KOH/ g
Iodine colour value	AM-25	70
Total Plate Count	ISO 4833-1 modified	<40 / g
Yeast	ISO 7954 modified	<10 / g
Mould	ISO 7954 modified	<20 / g
Enterobacteriaceae	0053-Mi	negative / g
Salmonella	ISO 6579 (25g)	negative

Hamburg, 4. Oktober 2016

computer/electronically printed and therefore no signature

Certificate of Analysis

Product: **DP 1046**
Batch: **8-6-3007**
Manufacturing date: **03/ 2016**
Best before: **03/ 2017**

Parameter	Method	Actual Value
Aceton Insolubles	AM-22	98,7 %
Toluen Insolubles	AM-36	0,07 %
Hexane Insolubles	AM-36	0,07 %
Moisture	AM-30	0,30 %
Peroxide value	AM-24	<1 meq / kg
Acid value	AM-28	23,1 mg KOH/ g
Iodine colour value	AM-25	65
Total Plate Count	MB 2.1	10 / g
Yeast	MB 3.1	negative / g
Mould	MB 3.1	negative / g
Enterobacteriaceae	MB 4.2.1 + MB 4.3 or Enterotube	negative / g
Salmonella	RT-PCR	negative / 50 g

Hamburg, 4. Oktober 2016

computer/electronically printed and therefore no signature

Certificate of Analysis

Product: **DP 1046**
Batch: **863016**
Manufacturing date: **07/ 2016**
Best before: **07/ 2017**

Parameter	Method	Actual Value
Aceton insolubles	AM-22	97,7 %
Toluen insolubles	AM-36	0,04 %
Hexane Insolubles	AM-36	0,02 %
Moisture	AM-30	0,55 %
Peroxide value	AM-24	<1 meq / kg
Acid value	AM-28	23,2 mg KOH/ g
Iodine colour value	AM-25	70 - 80
Total Plate Count	MB 2.1	100 / g
Yeast	MB 3.1	negative / g
Mould	MB 3.1	negative / g
Enterobacteriaceae	MB 4.2.1 + MB 4.3 or Enterotube	negative / 25g
Salmonella	RT-PCR	negative / 375 g

Hamburg, 4. Oktober 2016

computer/electronically printed and therefore no signature

Certificate of Analysis

Product: **DP 1046**
Batch: **102493**
Manufacturing date: **04/ 2016**
Best before: **04/ 2017**

Parameter	Method	Actual Value
Aceton insolubles	AM-22	97,3 %
Toluen insolubles	AM-36	0,05 %
Hexane Insolubles	AM-36	0.05 %
Moisture	AM-30	0,95 %
Peroxide value	AM-24	<1 meq / kg
Acid value	AM-28	23,5 mg KOH/ g
Iodine colour value	AM-25	75
Total Plate Count	MB 2.1	100 / g
Yeast	MB 3.1	negative / g
Mould	MB 3.1	negative / g
Enterobacteriaceae	MB 4.2.1 + MB 4.3 or Enterotube	negative / g
Salmonella	RT-PCR	negative / 375 g

Hamburg, 4. Oktober 2016

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Person in charge Mrs C. Blaszk - 2912
Client support Mrs C. Blaszk - 2912

Report date 01.11.2016

Analytical report: AR-16-JC-036968-04

This report replaces report number: AR-16-JC-036968-03

Sample Code 706-2016-00454595

Reference	Flüssiges Lecithin Louis D. Tank: lec 02.16.15 Date: 19.02.2016
Client Sample Code	QC Nr.: 350 - lec 02.16.2016
Number	1
Amount	1246 g
Reception temperature	room temperature
Ordered by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Submitted by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Sender	UPS
Reception date time	07.03.2016
Packaging	plastic tube with screw closure
Start/end of analyses	08.03.2016 / 15.03.2016

TEST RESULTS

Physical-chemical Analysis

J1001	**Sample preparation (#)**			
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)			
J8306	**Lead (Pb) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Lead (Pb)		<0.05	*	mg/kg
J8308	**Cadmium (Cd) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Cadmium (Cd)		<0.01	*	mg/kg
JCHG2	**Mercury (Hg) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Mercury (Hg)		<0.005	*	mg/kg
J8312	**Arsenic (As) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Arsenic (As)		<0.1	*	mg/kg
J1042	**Copper (Cu) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Copper (Cu)		0.2		mg/kg
J1043	**Iron (Fe) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Iron (Fe)		16		mg/kg

This report replaces report number: AR-16-JC-036968-03

J1049	**Nickel (Ni) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Nickel (Ni)		0.2		mg/kg
J1061	**Zinc (Zn) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Zinc (Zn)		2.2		mg/kg
J1057	**Tin (Sn) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Tin (Sn)		<0.5	*	mg/kg
J1032	**Aluminium (Al) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Aluminium		<0.5	*	mg/kg
J1047	**Manganese (Mn) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Manganese (Mn)		5.3		mg/kg
J1048	**Sodium (Na) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Sodium (Na)		10		mg/kg
J1045	**Potassium (K) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Potassium (K)		4100		mg/kg
J1046	**Magnesium (Mg) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Magnesium (Mg)		1500		mg/kg
J1038	**Calcium (Ca) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Calcium (Ca)		2800		mg/kg
SP413	**Organochlorine Pesticides**			
Method:	ASU L00.00-34, DFG-S19, GC-ECD			
Subcontracted to a Eurofins laboratory accredited for this test.				
Screened pesticides		Not Detected		
SP421	**Organochlorine Pesticides, Pyrethroides**			
Method:	ASU L00.00-34, DFG-S19 , GC-ECD			
Subcontracted to a Eurofins laboratory accredited for this test.				
Screened pesticides		Not Detected		
SP414	**Pesticides LC-OP**			
Method:	ASU L00.00-34, DFG-S19, LC-MS/MS			
Subcontracted to a Eurofins laboratory accredited for this test.				
Screened pesticides		Not Detected		
AS406	**Dithiocarbamates (incl. Propineb) (Baby Food)**			
Method:	EN 12396-3:2000, P-14.008, Spectrophotometry (UV/VIS)			
Subcontracted to a Eurofins laboratory accredited for this test.				
Dithiocarbamates (as CS2)		< 0.005		mg/kg
S1006	**Phenoxycarboxylic acids**			
Method:	Internal method, P-14.098, GC-MS			
Subcontracted to a Eurofins laboratory accredited for this test.				
Other screened pesticides		Not Detected		
Haloxyfop (total, after hydrolysis)		0.040		mg/kg
SPGZ5	**Organotin Pesticides**			
Method:	Internal method, P-14.089, GC-MS			
Subcontracted to a Eurofins laboratory accredited for this test.				
Cyhexatin		< 0.05		mg/kg
Fenbutatin oxide		< 0.05		mg/kg
Fentine acetate/hydroxyde		< 0.01		mg/kg

This report replaces report number: AR-16-JC-036968-03

SPSF7	**Fipronil**		
Method:	EN 15662:2008, P-14.141, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Fipronil		< 0.003	mg/kg
Fipronil, desulfinyl-		< 0.003	mg/kg
Fipronil-sulfide		< 0.003	mg/kg
Fipronil-sulfone		< 0.003	mg/kg
SPSEP	**Propylene thiourea (PTU) and Ethylene thiourea (ETU)**		
Method:	Internal method, P-14.065, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Ethylene thiourea (ETU)		< 0.01	mg/kg
PTU (Propylene Thiourea)		< 0.01	mg/kg
JCAF2	**Aflatoxins B1, B2, G1, G2 (fats, oils, lecithin, egg powder) (#)**		
Method:	internal method based on EN 14123, CON-PV-00873, IAC-LC-FLD		
Aflatoxin B1		<0.1	* µg/kg
Aflatoxin B2		<0.1	* µg/kg
Aflatoxin G1		<0.1	* µg/kg
Aflatoxin G2		<0.1	* µg/kg
Sum of all positive Aflatoxins		<0.4	* µg/kg
JC0F2	**Ochratoxin A (fat, oil, lecithin, egg powder) (#)**		
Method:	CEN 14132, mod., CON-PV-00850, IAC-LC-FLD		
Ochratoxin A (OTA)		<0.2	* µg/kg
JJ62B	**Deoxynivalenol, Zearalenon (DON, ZON) (#)**		
Method:	Internal method, CON-PV 01126, LC-MS/MS		
Deoxynivalenol (Vomitoxin)		<20	* µg/kg
Zearalenone (ZON)		<10	* µg/kg

* = Below indicated quantification level

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

Signature (b) (6)

Analytical Service Manager (Carolina Blaszk)

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Person in charge Mrs C. Blaszk - 2912
Client support Mrs C. Blaszk - 2912

Report date 01.11.2016

Analytical report: AR-16-JC-083515-04

This report replaces report number: AR-16-JC-083515-03

Sample Code 706-2016-00501281

Reference	Rapslecithin LD12.04.2016 B82
Client Sample Code	QC-Nr. 786 -#10316HSDBA
Number	1
Amount	1134 g
Reception temperature	room temperature
Ordered by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Submitted by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Sender	UPS
Reception date time	06.06.2016
Packaging	Kunststoffbehälter mit Schraubverschluss
Start/end of analyses	08.06.2016 / 15.06.2016

TEST RESULTS

Physical-chemical Analysis

J1001	**Sample preparation (#)**			
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)			
J8306	**Lead (Pb) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Lead (Pb)		<0.05	*	mg/kg
J8308	**Cadmium (Cd) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Cadmium (Cd)		<0.01	*	mg/kg
JCHG2	**Mercury (Hg) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Mercury (Hg)		<0.005	*	mg/kg
J8312	**Arsenic (As) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Arsenic (As)		<0.1	*	mg/kg
J1042	**Copper (Cu) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Copper (Cu)		0.2		mg/kg
J1043	**Iron (Fe) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Iron (Fe)		14		mg/kg

This report replaces report number: AR-16-JC-083515-03

J1049	**Nickel (Ni) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Nickel (Ni)		<0.5	* mg/kg
J1061	**Zinc (Zn) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Zinc (Zn)		2.7	mg/kg
J1057	**Tin (Sn) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Tin (Sn)		<0.5	* mg/kg
J1032	**Aluminium (Al) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Aluminium		<0.5	* mg/kg
J1047	**Manganese (Mn) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Manganese (Mn)		5.8	mg/kg
J1048	**Sodium (Na) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Sodium (Na)		10	mg/kg
J1045	**Potassium (K) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Potassium (K)		4500	mg/kg
J1046	**Magnesium (Mg) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Magnesium (Mg)		1600	mg/kg
J1038	**Calcium (Ca) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Calcium (Ca)		2900	mg/kg
SP413	**Organochlorine Pesticides**		
Method:	ASU L00.00-34, DFG-S19, GC-ECD		
Subcontracted to a Eurofins laboratory accredited for this test.			
Screened pesticides		Not Detected	
SP421	**Organochlorine Pesticides, Pyrethroides**		
Method:	ASU L00.00-34, DFG-S19 , GC-ECD		
Subcontracted to a Eurofins laboratory accredited for this test.			
Screened pesticides		Not Detected	
SP414	**Pesticides LC-OP**		
Method:	ASU L00.00-34, DFG-S19, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Screened pesticides		Not Detected	
AS406	**Dithiocarbamates (incl. Propineb) (Baby Food)**		
Method:	EN 12396-3:2000, P-14.008, Spectrophotometry (UV/VIS)		
Subcontracted to a Eurofins laboratory accredited for this test.			
Dithiocarbamates (as CS2)		< 0.005	mg/kg
S1006	**Phenoxycarboxylic acids**		
Method:	Internal method, P-14.098, GC-MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Other screened pesticides		Not Detected	
Haloxyfop (total, after hydrolysis)		0.010	mg/kg
SPGZ5	**Organotin Pesticides**		
Method:	Internal method, P-14.089, GC-MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Cyhexatin		< 0.05	mg/kg
Fenbutatin oxide		< 0.05	mg/kg
Fentine acetate/hydroxyde		< 0.01	mg/kg

Analytical report: AR-16-JC-083515-04
Sample Code 706-2016-00501281

This report replaces report number: AR-16-JC-083515-03

SPSF7	**Fipronil**		
Method:	EN 15662:2008, P-14.141, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Fipronil		< 0.003	mg/kg
Fipronil, desulfinyl-		< 0.003	mg/kg
Fipronil-sulfide		< 0.003	mg/kg
Fipronil-sulfone		< 0.003	mg/kg
SPSEP	**Propylene thiourea (PTU) and Ethylene thiourea (ETU)**		
Method:	Internal method, P-14.065, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Ethylene thiourea (ETU)		< 0.01	mg/kg
PTU (Propylene Thiourea)		< 0.01	mg/kg
JCAF2	**Aflatoxins B1, B2, G1, G2 (fats, oils, lecithin, egg powder) (#)**		
Method:	internal method based on EN 14123, CON-PV-00873, IAC-LC-FLD		
Aflatoxin B1		<0.1	* µg/kg
Aflatoxin B2		<0.1	* µg/kg
Aflatoxin G1		<0.1	* µg/kg
Aflatoxin G2		<0.1	* µg/kg
Sum of all positive Aflatoxins		<0.4	* µg/kg
JC0F2	**Ochratoxin A (fat, oil, lecithin, egg powder) (#)**		
Method:	CEN 14132, mod., CON-PV-00850, IAC-LC-FLD		
Ochratoxin A (OTA)		<0.2	* µg/kg
JJ62B	**Deoxynivalenol, Zearalenon (DON, ZON) (#)**		
Method:	Internal method, CON-PV 01126, LC-MS/MS		
Deoxynivalenol (Vomitoxin)		<20	* µg/kg
Zearalenone (ZON)		<10	* µg/kg

* = Below indicated quantification level

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

Signature (b) (6)

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Person in charge Mrs C. Blaszk - 2912
Client support Mrs C. Blaszk - 2912

Report date 01.11.2016

Analytical report: AR-16-JC-083788-05

This report replaces report number: AR-16-JC-083788-04

Sample Code 706-2016-00501282

Reference	entöltes Rapslecithinpulver DP1046
Client Sample Code	QC-Nr. 785 - # 102493
Number	1
Amount	1179 g
Reception temperature	room temperature
Ordered by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Submitted by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Sender	UPS
Reception date time	06.06.2016
Packaging	Kunststoffbehälter mit Schraubverschluss
Start/end of analyses	08.06.2016 / 16.06.2016

TEST RESULTS

Physical-chemical Analysis

J1001	**Sample preparation (#)**			
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)			
J8306	**Lead (Pb) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Lead (Pb)		<0.05	*	mg/kg
J8308	**Cadmium (Cd) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Cadmium (Cd)		<0.01	*	mg/kg
JCHG2	**Mercury (Hg) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Mercury (Hg)		<0.005	*	mg/kg
J8312	**Arsenic (As) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Arsenic (As)		<0.1	*	mg/kg
J1042	**Copper (Cu) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Copper (Cu)		0.3		mg/kg
J1043	**Iron (Fe) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Iron (Fe)		25		mg/kg

This report replaces report number: AR-16-JC-083788-04

J1049	**Nickel (Ni) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Nickel (Ni)		0.2	mg/kg
J1061	**Zinc (Zn) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Zinc (Zn)		3.9	mg/kg
J1057	**Tin (Sn) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Tin (Sn)		<0.5	* mg/kg
J1032	**Aluminium (Al) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Aluminium		0.7	mg/kg
J1047	**Manganese (Mn) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Manganese (Mn)		9.0	mg/kg
J1048	**Sodium (Na) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Sodium (Na)		12	mg/kg
J1045	**Potassium (K) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Potassium (K)		7100	mg/kg
J1046	**Magnesium (Mg) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Magnesium (Mg)		2600	mg/kg
J1038	**Calcium (Ca) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Calcium (Ca)		4600	mg/kg
SP413	**Organochlorine Pesticides**		
Method:	ASU L00.00-34, DFG-S19, GC-ECD		
Subcontracted to a Eurofins laboratory accredited for this test.			
Screened pesticides		Not Detected	
SP421	**Organochlorine Pesticides, Pyrethroides**		
Method:	ASU L00.00-34, DFG-S19 , GC-ECD		
Subcontracted to a Eurofins laboratory accredited for this test.			
Screened pesticides		Not Detected	
SP414	**Pesticides LC-OP**		
Method:	ASU L00.00-34, DFG-S19, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Screened pesticides		Not Detected	
AS406	**Dithiocarbamates (incl. Propineb) (Baby Food)**		
Method:	EN 12396-3:2000, P-14.008, Spectrophotometry (UV/VIS)		
Subcontracted to a Eurofins laboratory accredited for this test.			
Dithiocarbamates (as CS2)		< 0.005	mg/kg
S1006	**Phenoxycarboxylic acids**		
Method:	Internal method, P-14.098, GC-MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Screened pesticides		Not Detected	
SPGZ5	**Organotin Pesticides**		
Method:	Internal method, P-14.089, GC-MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Cyhexatin		< 0.05	mg/kg
Fenbutatin oxide		< 0.05	mg/kg
Fentine acetate/hydroxyde		< 0.01	mg/kg

This report replaces report number: AR-16-JC-083788-04

SPSF7	**Fipronil**		
Method:	EN 15662:2008, P-14.141, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Fipronil		< 0.003	mg/kg
Fipronil, desulfinyl-		< 0.003	mg/kg
Fipronil-sulfide		< 0.003	mg/kg
Fipronil-sulfone		< 0.003	mg/kg
SPSEP	**Propylene thiourea (PTU) and Ethylene thiourea (ETU)**		
Method:	Internal method, P-14.065, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Ethylene thiourea (ETU)		< 0.01	mg/kg
PTU (Propylene Thiourea)		< 0.01	mg/kg
JCAF2	**Aflatoxins B1, B2, G1, G2 (fats, oils, lecithin, egg powder) (#)**		
Method:	internal method based on EN 14123, CON-PV-00873, IAC-LC-FLD		
Aflatoxin B1		<0.1	* µg/kg
Aflatoxin B2		<0.1	* µg/kg
Aflatoxin G1		<0.1	* µg/kg
Aflatoxin G2		<0.1	* µg/kg
Sum of all positive Aflatoxins		<0.4	* µg/kg
JC0F2	**Ochratoxin A (fat, oil, lecithin, egg powder) (#)**		
Method:	CEN 14132, mod., CON-PV-00850, IAC-LC-FLD		
Ochratoxin A (OTA)		<0.2	* µg/kg
JJ62B	**Deoxynivalenol, Zearalenon (DON, ZON) (#)**		
Method:	Internal method, CON-PV 01126, LC-MS/MS		
Deoxynivalenol (Vomitoxin)		<20	* µg/kg
Zearalenone (ZON)		<10	* µg/kg

* = Below indicated quantification level

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

Signature (b) (6)

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Client support Mrs C. Blaszk - 2912

Report date 01.11.2016

Analytical report: AR-16-JC-095642-04

This report replaces report number: AR-16-JC-095642-03

Sample Code 706-2016-00513064

Reference	Rapslecithin
Client Sample Code	QC-Nr. 917 - 488-5
Number	1
Amount	1238 g
Reception temperature	room temperature
Ordered by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Submitted by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Sender	UPS
Reception date time	28.06.2016
Start/end of analyses	28.06.2016 / 08.07.2016

TEST RESULTS

Physical-chemical Analysis			
J1001	**Sample preparation (#)**		
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)		
J8306	**Lead (Pb) (#)**		
Method:	EN 15763:2009, CON-PV 01274, ICP-MS		
Lead (Pb)		<0.05	* mg/kg
J8308	**Cadmium (Cd) (#)**		
Method:	EN 15763:2009, CON-PV 01274, ICP-MS		
Cadmium (Cd)		<0.01	* mg/kg
JCHG2	**Mercury (Hg) (#)**		
Method:	EN 15763:2009, CON-PV 01274, ICP-MS		
Mercury (Hg)		<0.005	* mg/kg
J8312	**Arsenic (As) (#)**		
Method:	EN 15763:2009, CON-PV 01274, ICP-MS		
Arsenic (As)		<0.1	* mg/kg
JJW2B	**Copper (Cu) (#)**		
Method:	DIN EN ISO 17294-2-E29, CON-PV 00857, ICP-MS		
Copper (Cu)		0.3	mg/kg
J1043	**Iron (Fe) (#)**		
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES		
Iron (Fe)		16	mg/kg

This report replaces report number: AR-16-JC-095642-03

JJ0CM	**Nickel (Ni) (#)**			
Method:	DIN EN ISO 17294-2-E29, CON-PV 00857, ICP-MS			
Nickel (Ni)		<0.1	*	mg/kg
J1061	**Zinc (Zn) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Zinc (Zn)		2.5		mg/kg
JJ0CV	**Tin (Sn) (#)**			
Method:	DIN EN ISO 17294-2-E29, CON-PV 00857, ICP-MS			
Tin (Sn)		<0.2	*	mg/kg
JJ0CT	**Aluminium (Al) (#)**			
Method:	DIN EN ISO 17294-2-E29, CON-PV 00857, ICP-MS			
Aluminium		<0.5	*	mg/kg
J1047	**Manganese (Mn) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Manganese (Mn)		5.8		mg/kg
J1048	**Sodium (Na) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Sodium (Na)		100		mg/kg
J1045	**Potassium (K) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Potassium (K)		4500		mg/kg
J1046	**Magnesium (Mg) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Magnesium (Mg)		1600		mg/kg
J1038	**Calcium (Ca) (#)**			
Method:	DIN EN ISO 11885, mod., CON-PV 00006, ICP-OES			
Calcium (Ca)		2900		mg/kg
SP413	**Organochlorine Pesticides**			
Method:	ASU L00.00-34, DFG-S19, GC-ECD			
Subcontracted to a Eurofins laboratory accredited for this test.				
Screened pesticides		Not Detected		
SP421	**Organochlorine Pesticides, Pyrethroides**			
Method:	ASU L00.00-34, DFG-S19 , GC-ECD			
Subcontracted to a Eurofins laboratory accredited for this test.				
Screened pesticides		Not Detected		
SP414	**Pesticides LC-OP**			
Method:	ASU L00.00-34, DFG-S19, LC-MS/MS			
Subcontracted to a Eurofins laboratory accredited for this test.				
Screened pesticides		Not Detected		
AS406	**Dithiocarbamates (incl. Propineb) (Baby Food)**			
Method:	EN 12396-3:2000, P-14.008, Spectrophotometry (UV/VIS)			
Subcontracted to a Eurofins laboratory accredited for this test.				
Dithiocarbamates (as CS2)		< 0.005		mg/kg
S1006	**Phenoxycarboxylic acids**			
Method:	Internal method, P-14.098, GC-MS			
Subcontracted to a Eurofins laboratory accredited for this test.				
Screened pesticides		Not Detected		
SPGZ5	**Organotin Pesticides**			
Method:	Internal method, P-14.089, GC-MS			
Subcontracted to a Eurofins laboratory accredited for this test.				
Cyhexatin		< 0.05		mg/kg
Fenbutatin oxide		< 0.05		mg/kg
Fentine acetate/hydroxyde		< 0.01		mg/kg

This report replaces report number: AR-16-JC-095642-03

SPSF7	**Fipronil**		
Method:	EN 15662:2008, P-14.141, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Fipronil		< 0.003	mg/kg
Fipronil, desulfinyl-		< 0.003	mg/kg
Fipronil-sulfide		< 0.003	mg/kg
Fipronil-sulfone		< 0.003	mg/kg
SPSEP	**Propylene thiourea (PTU) and Ethylene thiourea (ETU)**		
Method:	Internal method, P-14.065, LC-MS/MS		
Subcontracted to a Eurofins laboratory accredited for this test.			
Ethylene thiourea (ETU)		< 0.01	mg/kg
PTU (Propylene Thiourea)		< 0.01	mg/kg
JCAF2	**Aflatoxins B1, B2, G1, G2 (fats, oils, lecithin, egg powder) (#)**		
Method:	internal method based on EN 14123, CON-PV-00873, IAC-LC-FLD		
Aflatoxin B1		<0.1	* µg/kg
Aflatoxin B2		<0.1	* µg/kg
Aflatoxin G1		<0.1	* µg/kg
Aflatoxin G2		<0.1	* µg/kg
Sum of all positive Aflatoxins		<0.4	* µg/kg
JC0F2	**Ochratoxin A (fat, oil, lecithin, egg powder) (#)**		
Method:	CEN 14132, mod., CON-PV-00850, IAC-LC-FLD		
Ochratoxin A (OTA)		<0.2	* µg/kg
JJ62B	**Deoxynivalenol, Zearalenon (DON, ZON) (#)**		
Method:	Internal method, CON-PV 01126, LC-MS/MS		
Deoxynivalenol (Vomitoxin)		<20	* µg/kg
Zearalenone (ZON)		<10	* µg/kg

* = Below indicated quantification level

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

Signature (b) (6)

Analytical Service Manager (Carolina Blaszk)

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Report date 04.10.2016
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Analytical report: AR-16-JC-098297-02

This report replaces report number: AR-16-JC-098297-01

Sample Code 706-2016-00517309

Reference	Entöltes Rapslecithin
Client Sample Code	QC-Nr. 948 863016
Number	1
Amount	69 g
Reception temperature	room temperature
Ordered by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Submitted by	Cargill Texturizing Solutions Deutschland GmbH & Co. KG
Sender	UPS
Reception date time	06.07.2016
Packaging	plastic container with screw cap
Start/end of analyses	06.07.2016 / 15.07.2016

TEST RESULTS

Physical-chemical Analysis

J1001	**Sample preparation (#)**			
Method:	§64 LFGB L 00.00-19/1, CON-PV 00001, Digestion (microwave)			
JCHRA	**Lead (Pb) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-HRMS			
Lead (Pb)		48		µg/kg
JCHG2	**Mercury (Hg) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Mercury (Hg)		<0.005	*	mg/kg
J8312	**Arsenic (As) (#)**			
Method:	EN 15763:2009, CON-PV 01274, ICP-MS			
Arsenic (As)		<0.1	*	mg/kg

* = Below indicated quantification level
(#) = Eurofins WEJ Contaminants GmbH (Hamburg) is accredited for this test.

Signature (b) (6)

Analytical Service Manager (Carolina Blaszk)

EXHIBIT I

Report of the Expert Panel

OPINION OF AN EXPERT PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CANOLA LECITHIN FOR USE IN FOOD

Introduction

An independent panel of experts (Expert Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by Cargill, Incorporated (Cargill) to determine the safety and Generally Recognized as Safe (GRAS) status of the use of canola lecithin in food for human consumption. Canola lecithin is intended for use as a nutritional ingredient and as an emulsifier, surfactant, and dispersing agent in foods. The canola lecithin ingredient is manufactured in accordance with current Good Manufacturing Practice (cGMP) and meets the proposed specifications.

A detailed review based on the existing scientific literature (through September 2016) on the safety of canola lecithin was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The Expert Panel members reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on November 14, 2016 via teleconference. Based on an independent, critical evaluation of all of the available information and discussions during the November 14, 2016 teleconference, the Expert Panel unanimously concluded that the intended uses described herein for Cargill's canola lecithin ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of Canola Lecithin for Use in Food**) and manufactured according to cGMP, are safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the Expert Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

Lecithin is a natural complex mixture of acetone-insoluble phosphatides that consists mainly of phosphatidylcholine, phosphatidylethanolamine, phosphatidylinositol, and phosphatidic acid, as well diverse amounts of other substances such as triglycerides, fatty acids, and carbohydrates. Cargill's canola lecithin uses only double zero (00) canola seed to produce canola lecithin. Based on Cargill's liquid canola analyses, the erucic acid content (C22:1) is an average of 0.1% and as such, "canola" refers to low-erucic acid rapeseed. The fluid form of canola lecithin is green-brown in appearance. It is soluble in hexane, toluene, chlorinated hydrocarbons, in addition to oils and fats. Lecithin powder, which typically appears as beige color, is a mixture of polar (phospho- and glyco-) lipids and a small amount of carbohydrates.

Manufacturing Process

Processing of Crude Lecithin

The production of canola lecithin is similar to that of other plant-derived lecithins. The process begins with the conventional preparation of canola through cleaning, drying, tempering, conditioning, flaking, and pressing of the canola seed. The seed is then run through an expander or expeller.

To remove any remaining oil after extraction, the pressed canola seeds (cake) are treated with hexane that is specially refined for the vegetable oil industry. The cake is flooded with solvent or miscella (canola oil plus hexane). Next, the extractor moves the cake and the miscella (solvent plus oil) in opposite directions to create a continuous counter-current extraction.

A series of pumps spray miscella over the cake, gradually increasing the ratio of solvent to oil. The solvent percolates by gravity through the cake, diffusing into and eventually saturating the cake fragments. After a fresh solvent wash, the hexane-saturated meal leaving the solvent extractor contains less than 1% oil. The most commonly used extractors are baskets with a continuous-loop design.

After extraction, it is common to use miscella filtration, in which the mixture of oil, lecithin, and hexane is run via prefiltration to obtain a size in the range of 50–100 μm, followed by diatomaceous earth filtration. During the de-solventizing step, the miscella are steam stripped and evaporated from the cake.

The crude canola oil is heated to about 70°C during the degumming process, mixed with 2% water, and then subjected to thorough stirring for about 30 minutes to one hour. The exact temperature, amount of water added, and mixing times vary among the various extraction plants, but all plants produce the ingredient within specifications. The addition of water to the oil hydrates the polar lipids in the oil, making them insoluble and resulting in a lecithin sludge that must be separated by centrifugation. The wet sludge is made up of water, phospholipids, and glycolipids, some triglycerides, carbohydrates, traces of sterols, free fatty acids, and carotenoids.

The crude canola lecithin is then obtained by careful drying using mainly thin-film evaporators to dry the gums. After drying, the crude lecithin can by altered by addition of canola oil or/and canola fatty acid to meet the specified canola lecithin quality.

De-Oiling with Acetone to Manufacture Powdered Lecithin

Crude lecithin contains about 30%–40% neutral lipids, mainly triglycerides. To improve the processing characteristics and dispersant properties of high-viscosity crude lecithin, acetone extraction is performed to remove neutral lipids, mainly triglycerides, and obtain polar lipids, such as phospholipids and glycolipids. By utilizing an extraction with acetone, a de-oiled lecithin with a residual content of only 2%–3% neutral lipids is

produced. The resulting products can be made into powder or granulated forms and display a significant improvement in emulsifying capacity and in dispersibility in water. The key element of the de-oiling process is that the phospholipids, as the components that provide functionality, have now been concentrated and purified. This results in significantly lower use level requirements and higher functionality. In addition, the de-oiled products have a more neutral taste than the corresponding liquid products, because most of the aroma components are removed with the acetone.

Standardization

The composition of lecithins may vary considerably depending on the raw material source. Even more specifically for canola lecithin, the canola variety, the geographic region, weather, storage, and processing conditions can have a significant influence on the various quality aspects of lecithins produced.

The various constituents of lecithins (phospholipids) contribute in different ways to the functionality of lecithin in the final application; therefore, it is reasonable to standardize the final lecithin products in order to guarantee a consistent composition, and thereby its functionality. Also the total phospholipid contents may vary significantly and may need to be adjusted.

Analytical (physical, chemical and microbiological) results for the canola lecithin product confirm that the finished product meets the proposed specifications as demonstrated by the consistency of production, the lack of impurities and contaminants (e.g., heavy metals, pesticides, microorganisms (*Salmonella* and *E. coli*), and mycotoxins). Further, the data provided from the analyses of the three non-consecutive lots consistently demonstrate that the specifications established for Cargill's canola lecithin product meet or exceed the published Food Chemical Codex (FCC) specifications.

Similar to other Cargill plant-based lecithin ingredients, the recommended shelf life for both the fluid and powder forms of canola lecithin is a minimum of 12 months. Stability testing of the proposed canola lecithin ingredient is ongoing. The recommended storage conditions are to reclose packaging immediately after opening. Store in a dry place between 15 and 30°C (59 to 86°F) for fluid lecithin and <25°C (<77°F) for de-oiled lecithin, and store in its original packaging until used.

History of Use

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

> 21 CFR § 184.1400 Lecithin
>
> (a) Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn

oils. Lecithin is bleached, if desired, by hydrogen peroxide and benzoyl peroxide and dried by heating.

(b) The ingredient meets the specifications as first reported in the Food Chemicals Codex, 3d Ed. (1981), pp. 166-167, which is incorporated by reference.

(c) In accordance with 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Lecithin was discovered in 1846, and industrial production began in the 1920s when an extraction process from plant sources was implemented. Numerous lecithin ingredients from other plant or grain sources are recognized as GRAS for their intended uses in foods, and the following lecithin ingredients listed have received "no questions" letters from the United States Food and Drug Administration (FDA); hydrogenated lecithin from soy (GRAS notification (GRN 637), lecithin from canola (GRN 533), lecithin derived from krill (GRN 226), soy lecithin enzymatically modified to contain increased phosphatidylserine (GRN 186), and soy protein hydrolysate with enzyme-modified lecithin (GRN 134).

Intended Use and Intake Assessment

Canola lecithin is intended for addition to foods as a nutritional ingredient and as an emulsifier; wetting or instantizing agent; viscosity modifier; releasing agent; extrusion aid; low-flavor binding material; and high-quality dietary fat source. According to 21 CFR § 184.1400, lecithin that is solvent-extracted from soy, safflower, or corn oils can be used without limitation other than cGMPs. Cargill's canola lecithin is intended for use as an alternative lecithin source to lecithins derived from other plant sources and will be employed in a similar fashion.

Cargill's canola lecithin product is intended for use as an alternative source of lecithin in all currently approved food categories (including as an emulsifying agent in meat and poultry; 9 CFR § 424.1) in accordance with cGMP. As described in numerous GRAS Notifications, including GRN No. 533 for canola lecithin, the typical uses of lecithin in foods include but are not limited to baked goods, dairy products, milk analog beverages, breakfast cereals, pasta, confections, soups, stews, chili, ice cream/frozen desserts, margarines/spreads, ovenable breadings and coatings, frostings, non-dairy creamer, sauces/gravies, and as a dietary source of choline in milk-based non-exempt infant formula for term infants at levels up to 3 grams (g) per 100 g. GRN 533 estimated the average dietary exposure to canola lecithin from the intended food uses and use levels to be 6.8-9.5 g per person per day (i.e., equivalent to 113-160 mg/kg bw/day for a 60 kg adult and 226-320 mg/kg bw/day for a 30 kg child).

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

Safety Data

Lecithin is a direct food substance affirmed as GRAS in 21 CFR § 184.1400, which states that "commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of othe[r] lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils." According to 21 CFR § 184.1400, lecithin from soy, safflower, or corn oils can be used in food with no limitation other than cGMP. Canola oil is proposed as an alternative source of lecithin, and the canola lecithin that is the subject of the GRAS determination would be added to food in a manner similar to the oil sources cited in 21 CFR § 184.1400. The identity of the Cargill canola-derived lecithin is nearly identical to the product considered GRAS in GRN 533 (FDA, 2014b), which received no questions from FDA, and is proposed for the same intended uses therein.

Enzyme-modified lecithin is also GRAS according to 21 CFR § 184.1063. Other sources for or derivatives of lecithin that have been notified as GRAS to FDA with "no questions" letters issued include krill-based (GRN 226; FDA, 2007)), soy lecithin phosphatidylserine complex (GRN 186; FDA, 2005), phosphatidylserine derived from sunflower lecithin or soy lecithin (GRN 545; FDA, 2014d), and soybean-derived hydrogenated lecithin (GRN 534; FDA, 2014c). In addition, lecithin is approved in 9 CFR § 424.21 for use as an emulsifying agent and antioxidant in oleomargarine, shortening, and various meat and poultry products.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974) evaluated lecithin in 1974 and concluded the acceptable daily intake to be "not limited." The European Commission Scientific Committee for Food (SCF) previously determined lecithins to be safe for use in foods and infant formula (SCF 1982, 1997). As part of Regulation (EC) No 1333/20081 of the European Parliament and of the Council on food additives the European Commission set up a program for the re-evaluation, by the European Food Safety Authority (EFSA), of the safety of food additives which were permitted in the European Union before 20 January 2009. As such, and in accordance with the above regulations, EFSA started a systematic re-evaluation of authorized food additives and is issuing scientific opinions on these food additives in accordance with the priorities indicated in the Commission Regulation (EU) No 257/2010. As part of this reevaluation undertaking, the European Food Safety Authority (EFSA) in 2015 issued a call for data on lecithins for a re-evaluation of use as additives to human foods (http://www.efsa.europa.eu/en/data/call/150608); no updated opinion based on any reevaluation has been published to date. However, EFSA has issued a Scientific Opinion on the safety and efficacy of lecithins for feed for all animal species, which concluded "the use of lecithins in animal nutrition does not pose any risk to the consumer" (EFSA, 2016). Finally, the Cosmetic Ingredient Review Panel (CIR, 2015) evaluated lecithins as

a class (including 17 phosphoglycerides) and concluded them to be "safe in the present practices of use and concentration in cosmetics, as described in this safety assessment"; use concentrations were reported to be up to 50% in leave-on products.

As noted above, the identity and composition of the Cargill canola lecithin is almost identical to that of other approved lecithin products and consistent with Food Chemicals Codex specifications (10th edition). It is also derived from low-erucic acid canola seed and therefore has a low erucic acid content. As fatty acids and phospholipids are common dietary components and constituents of cell membranes, minor differences in relative amounts present in lecithin products are of no safety concern in regard to the proposed canola lecithin product and its use in food. Generally, the difference in the fatty acid profile is the slightly higher concentration of mono-unsaturated oleic acid and lower concentration of di-unsaturated linoleic acid in the canola products. This variation in the oleic:linoleic ratio was acknowledged in GRN 533 and considered to be GRAS with a "no questions" letter received from FDA. Of note, a range of products and associated compositions were included in GRN 533, including a purified phosphatidylcholine product with 61.1% oleic acid, which is more than the oleic acid content of the Cargill product (range 55.3%–56.6%). In addition, high-oleic-acid cooking oils are part of the common diet (olive oil, canola oil-GRAS in 21 CFR § 184.1555), and related products have been notified as GRAS with "no questions" letters received from FDA; these include low-saturated, high-oleic, low-linolenic soybean oil (GRN 306-55%–85%; FDA, 2009) and of high-oleic *Prototheca moriformis* S2532 algal oil (GRN 527-86%–89%; FDA, 2014a). GRN 305 provides a comprehensive overview of the available human epidemiological and clinical data on the intake of oleic acid, concluding that no adverse outcomes were associated with higher intakes.

The safety of lecithins has been evaluated, and they have been deemed safe for human consumption by various organizations, as discussed above. It is important to note that the data used to support a safety conclusion in each of these evaluations varied widely. This variable approach is due to the composition and nature of lecithins. Given that lecithin is a mixture consisting of phospholipids (primarily phosphatidylcholine, phosphatidylethanolamine, phosphatidic acid, and phosphatidylinositol), fatty acids, and other minor components (e.g., triglycerides and carbohydrates), it is reasonable that an evaluation of any of these constituents is pertinent to a safety determination.

For example, JECFA (1974) included only a few studies of egg yolk phosphatides in animals and on lecithin administration in humans, concluding, "Although fewer toxicological studies have been conducted than would normally be required for substances used as food additives, it is considered that nutritional and clinical experience with lecithin is sufficiently extensive to compensate for the incompleteness of the experimental data." In 1979, the Select Committee on GRAS Substances (SCOGS) issued an opinion on lecithin, hydrogen peroxide bleached, and lecithin, based on a 2-year feeding study of lecithin in rats (Brantom et al., 1973) and exposures in humans. SCF (1982) in their evaluation similarly included a few studies on lecithin administration in rats. The EFSA Scientific Opinion on the safety and efficacy of lecithins for all animal species relied entirely on the data reported by CIR (2015; discussed below) and one other

study on phospholipids, and concluded that "[t]he toxicological data on lecithins showed no effects of concern and no indication of genotoxicity and carcinogenicity." The CIR Panel (2015) provided a comprehensive review of the available toxicokinetic and toxicological literature on lecithins and other phosphoglycerides in reaching its conclusion: these included lecithin, lysolecithin, lysohosphatidic acid, phosphatidylserine, phosphatidylcholine, phosphatidylethanalomine, phosphatidylinositol, hydrogenated lecithin, and phosphatidic acid.

Given the extensive reviews already performed and available, the safety sections of more recent GRNs have been limited in the additional safety data provided. For example, GRNs 533 and 534 reviewed only more recent data on the phosphatidylcholine degradation product, a-glycerylphosphorylcholine (AGPC); this GRN included acute, subchronic, and genetic toxicity. In the case of GRN 226 (FDA, 2007), the safety section addressed only potential differences in marine-derived phosphatidylcholine and associated lipids (focused on DHA and EPA) versus other approved phospholipids. No toxicological or additional safety data were discussed beyond the basic biochemistry of lecithin in the human body; the GRN noted that "the constituents of krill-based lecithin are commonly found in food" and did not discuss it further.

As described by Grundy (1987) and reviewed in GRNs 226 and 533 and EFSA (2016), dietary lecithin is generally absorbed in humans, with the majority being incorporated into the surface coat of chylomicrons. On ingestion, a small amount of lecithin is absorbed intact in the small intestines (primarily the duodenum and upper jejunum). The remaining majority of lecithin undergoes hydrolysis by pancreatic phospholipase A2, and the resulting lysolecithins and fatty acids are taken up by mucosal cells. Once taken up by mucosal cells, lysolecithin has been shown to undergo different processes: (1) re-esterification with a fatty acid (the resulting lecithin can be used in normal biological functions, such as becoming part of cell membranes or coating chylomicrons), (2) complete lipolysis (the released fatty acids can become triglycerides), or (3) absorption into portal circulation (Grundy, 1987).

Based on the biochemistry and fate of lecithins in the human body, lecithin derived from an alternative source, such as canola oil, would not be expected to have different toxicokinetic properties than other, plant-derived lecithins that have already been determined to be GRAS for human consumption. The safety reviews described above-by FDA in the CFR, SCOGS, SCF, GRNs, CIR, and EFSA—each involved a panel of qualified experts charged with reaching a conclusion regarding the safe use of a lecithin-related product for human use. These evaluations cover all toxicological endpoints relevant to the human oral consumption of lecithin (e.g., absorption, distribution, metabolism, and excretion [ADME], acute and repeated-dose oral toxicity, reproductive and developmental toxicity, genotoxicity, mutagenicity, carcinogenicity, and sensitization/allergenicity), and therefore, it can be considered that the totality of information available on lecithin and related compounds is sufficient to support the safe use of lecithin derived from canola oil for the proposed intended uses described herein.

Finally, it should be noted that a CIR panel (2015) raised a question concerning possible nitrosamine formation from the use of lecithin ingredients. The Expert Panel has considered the CIR report and concludes that the conditions under which nitrosamine formation could potentially occur are not consistent with food production or storage of food and are therefore not a concern in this assessment. Furthermore, the Expert Panel does not believe a cautionary statement for nitrosamines is required or that any concern about nitrosamines is warranted for this ingredient.

In summary, the safety of canola lecithin for the proposed uses in food has been demonstrated sufficiently in multiple previous evaluations conducted by qualified experts. The composition of the proposed canola lecithin product is nearly identical to other GRAS-notified lecithin ingredients derived from other plant sources. The constituents of canola lecithin are commonly consumed as part of a normal human diet. No relevant data published since 2015 were identified; however, the totality of information reviewed in already existing evaluations is sufficient to support the safe use of canola lecithin for the intended uses.

General Recognition of the Safety of Canola Lecithin

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

- The lecithin that is the subject of this notification is a mixture of acetone-insoluble phosphatides that consists mainly of phosphatidylcholine, phosphatidylethanolamine, phosphatidylinositol, and phosphatidic acid, as well as diverse amounts of other substances such as triglycerides, fatty acids, and carbohydrates derived from canola. The canola lecithin product is manufactured consistent with cGMP for food (21 CFR § 110 and § 117 Subpart B). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use as in food.

- The long history of lecithin consumption by humans is common knowledge. Numerous food products containing canola-derived lecithin and/or lecithin derived from other plant sources are marketed in the U.S. and around the world. Lecithin has become a desirable ingredient for addition to a variety of food products as a nutritional ingredient and as an emulsifier, wetting or instantizing agent, viscosity modifier, releasing agent, extrusion aid, low-flavor binding material, and high-quality dietary fat source.

- Lecithin is approved for use in food in 21 CFR § 184.1400 and it can be used in food with no limitation other than cGMP. Cargill's canola lecithin is intended for use as a source of lecithin that is an alternative to lecithins derived from other plant sources such as soy, corn, and sunflower. Numerous lecithin ingredients from other plant or grain sources are recognized as GRAS for their intended uses

in foods, including lecithin from canola, lecithin from krill, hydrogenated lecithin from soy, phosphatidylserine derived from soy lecithin, soy lecithin enzymatically modified to contain increased phosphatidylserine, and soy protein hydrolysate with enzyme-modified lecithin.

- Based on the biochemistry and fate of lecithins in the human body, it is not expected that lecithin derived from an alternative source such as canola oil would have toxicokinetic properties different from other plant-derived lecithins already determined to be GRAS for human consumption. Safety reviews by SCOGS, SCF, GRNs, CIR, and EFSA each involved a panel of qualified experts charged with reaching a conclusion regarding the safe use of a lecithin-related product for human use. The evaluations covered all toxicological endpoints relevant to human oral consumption of lecithin (e.g., ADME, acute and repeated-dose oral toxicity, reproductive and developmental toxicity, genotoxicity, mutagenicity, carcinogenicity, and sensitization/allergenicity).

- Regulatory authorities have reviewed studies on the composition and safety of various plant-derived lecithin products, including canola lecithin, and found no issues of concern with respect to their use in human food, including non-exempt infant formula.

- Therefore, the publicly available scientific literature on the consumption and safety of canola lecithin and lecithin ingredients is sufficient and supports the safety and GRAS status of the proposed canola lecithin product.

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Cargill's canola lecithin product. We conclude that the canola lecithin ingredient produced under the conditions described in the attached dossier and meeting the proposed specifications is safe.

We further unanimously conclude that the intended use of the canola lecithin product in specified foods for human consumption, meeting the specifications described above, is Generally Recognized as Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives, and critically evaluating the same information, would concur with these conclusions.

_____ _____

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

_____ _____

Stanley M. Tarka, Jr., Ph.D., F.A.T.S. Date
Consultant
Tarka Group, Inc.

_____ _____

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

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Cargill's canola lecithin product. We conclude that the canola lecithin ingredient produced under the conditions described in the attached dossier and meeting the proposed specifications is safe.

We further unanimously conclude that the intended use of the canola lecithin product in specified foods for human consumption, meeting the specifications described above, is Generally Recognized as Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives, and critically evaluating the same information, would concur with these conclusions.

(b) (6)

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SUBMISSION END