ADM
Quality Center of Excellence
4666 Faries Parkway Decatur, IL 62526
217.424.5200 | SIQA@adm.com

Ultralec® G Deoiled Lecithin

Technical Information

Product Code 700853

Product Description

Ultralec® deoiled lecithin is ideal for food and nutritional applications requiring a dry lecithin with a bland flavor and low aroma. The product is created by an exclusive ultrafiltration process that ensures unmatched quality and exceptional purity.

Applications

Ultralec® G is a source of phospholipids and essential fatty acids. It is generally consumed directly as a nutritional supplement. Other options include sprinkling it on yogurt and cereals or blending it in smoothies, for example. Ultralec® G is produced through a patented ultrafiltration process that does not use acetone to extract the oil. (Acetone extraction is the typical method for producing a deoiled lecithin.) Although the bulk of acetone is stripped from competitive products, residual acetone is always left in the final product. As the lecithin ages, acetone reacts through an aldol condensation to form highly odoriferous compounds such as mesityl oxide. Because Ultralec® G avoids the use of acetone, our process eliminates the off flavors and odors often associated with acetone-extracted deoiled lecithin.

Specification

Analysis, Typical	Limit	Method
% Acetone Insolubles, min.	97.0	AOCS
% Moisture, max.	1.5	AOCS
% Hexane Insolubles, max.	0.05	AOCS
Acid Value, max.	35	AOCS
Microbiological		
Total Plate Count, cfu/g max.	1000	FDA/BAM
Coliforms, cfu/g max.	3	FDA/BAM
Salmonella, in 375g	Negative	FDA/BAM
E.coli, in 11g	Negative	FDA/BAM
Yeast & Mold, cfu/g max.	30	FDA/BAM

Other Information

Ingredient Statement

Soy Lecithin

Regulatory Information

Country of Origin: United States
GRAS Affirmation: 21 CFR 184.1400
EU Food additive: E322
CAS #: 8030-76-0

Social Suitability

Kosher Pareve (OU certified)
Halal certified (IFANCA)
Vegetarian / Vegan compatible
Identity Preserved (IP) available

Available Pack Size

20-kg net weight boxes. 27 boxes per pallet
(1,188 lbs. net weight)
700853-GT

Other

HLB – Approx. 7

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Storage and Shelf Life

Storage temperature should not exceed 77°F (25°C). Product will meet FCC purity criteria for lecithin for a minimum 24 months from date of manufacture, when stored at or below 60°F (15°C) in the original container. Avoid excessive exposure to light and moisture.

Lot Coding

Lot code: **YYMMDDUBBB**

Example: 230101U001
This lot is the first batch packed on January 1, 2023.

YY	2-digit year code
MM	2-digit month code
DD	2-digit day code
U	Deoiled – Decatur Facility
BBB	sequential batch of the day

Packaging

The following information is in response to inquiries concerning compliance with (EC) No 1935/2004 concerning Materials Intended to Come into Contact with Food (framework), (EC) No 1895/2005 regarding Restriction of the use of certain epoxy derivatives in materials and articles intended to come into contact with food and linings, complies with migrations testing based on the methods give in EC 10/2011, and all product contact materials of these containers are in compliance with applicable FDA regulations. ADM has certifications on file from our suppliers that guarantee the packaging materials used comply, when applicable, with each of the above stated regulations.

Pallets

The pallets used by the ADM Soy Lecithin Division are food grade. The pallets are made of soft and hardwoods that are heat treated. Each pallet meets the ISP 15 Standard and will bear these markings on the side of the pallet. Each pallet will display the heat-treated mark, shown as “HT”.

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Typical Nutrition Information

Nutrient	/100g
Total Calories, kcal*	710
Calories from Fat	525
Calories from Saturated Fat	120
Total Fat*	58.4 g
Saturated Fat**	13.3 g
*Stearic****	2.1 g
*Palmitic****	10.2 g
Trans Fat**	0.1 g
Polyunsaturated Fat**	38.1 g
Linoleic [ω-6]	35.2 g
α-linolenic [ω-3]	4.6 g
Monounsaturated Fat**	4.3 g
*Oleic****	4.2 g
Cholesterol	0 mg
Sodium	7.4 mg
Potassium	1520 mg
Total Carbohydrate	8.2 g
Dietary Fiber	0 g
Sugars	4.0 g
Added Sugars	0 g
Protein	Trace
Vitamin D	0 mg
Calcium	114 mg
Iron	1.2 mg
Phosphorus	3210 mg
Vitamin E	18.0 IU

Other	/100g
Moisture***	0.8 g
Total Ash (includes Calcium, Iron and Phosphorus)***	16.1 g
Total Lipidic Material+	74.8 g

*Total Fat is reported as grams of Triglyceride
** Values are not reported as grams of Fatty Acid in the product, and as such, will not sum to grams of total Fat
*** Information provided for technical purposes and not required for inclusion by FDA/NLEA
+ Total Lipidic Material (g) = 100 – (Moisture (g) + Carbohydrate (g) + Ash (g)).
Typical Values

Major Phospholipid Content (%):	
Phosphatidylcholine	23
Phosphatidylethanolamine	18
Phosphatidylinositol	15
Phosphatic Acid	6
Choline (%)****	3.1

**** Choline is contained in the phosphatidylcholine.

Information from database and analytical sources is believed to be accurate as typical values of fluid lecithin.

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Allergen Information

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	US	CAN	EU	AUS NZ	JPN	Present in Final Product	Present in Production Line	Present in Production Facility	Cross Contamination Possible
Buckwheat					●	No	No	No	No
Celery and celeriac		●	●			No	No	No	No
Cereals with Gluten, such as wheat, rye, barley, oats, spelt, and triticale	●	●	●	●	●	No	No	No	No
Crustacean shellfish	●	●	●	●	●	No	No	No	No
Egg and egg products	●	●	●	●	●	No	No	No	No
Fish and fish products	●	●	●	●	●	No	No	No	No
Fruits and fruit products such as orange, kiwi, banana, peach, apple, mango, tomato					●	No	No	No	No
Gelatin and gelatin products					●	No	No	No	No
Latex and latex products						No	No	No	No
Lupin and lupin products			●	●		No	No	No	No
Meat and meat products such as beef, chicken, pork					●	No	No	No	No
Milk and dairy	●	●	●	●	●	No	No	No	No
Molluscan Shellfish	●	●	●	●	●	No	No	No	No
Mustard and mustard products		●	●			No	No	No	No
Matsutake mushrooms					●	No	No	No	No
Peanut and Peanut products	●	●	●	●	●	No	No	No	No
Sesame and sesame products	●	●	●	●		No	No	No	No
Soy or Soy products	●	●	●	●	●	Yes	Yes	Yes	Yes
Sulphur dioxide & Sulfites (>10ppm)	●	●	●	●	●	No	No	No	No
Tree nuts such as almond, brazil nut, cashew, hazelnut (filbert), macadamia, pecan, pine nut, pistachio and walnut	●	●	●	●	●	No	No	No	No
Yam and yam products					●	No	No	No	No

ADM Soy Lecithin facilities operate utilizing a closed, dedicated process with an Allergen Program in place.

Soy Lecithin does contain low levels of residual soy protein. Soy protein is listed as an allergen for susceptible persons. Soy Lecithin must be considered allergenic and should be labeled accordingly.

*Sulfites are not added during processing nor known to contain residuals of naturally occurring sulfites

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BSE (*Bovine Spongiform Encephalopathy*) and TSE (Transmissible Spongiform Encephalopathy)

Ultralec® Soy Lecithin products do not contain and are not processed, stored, packaged, or delivered with any animal products, by-products, or animal derived products.

Drug Substance / WADA

This document serves as verification that ADM Soy Lecithin products are not manufactured or warehoused with substances listed on the Annex C of the NSF 306-Certification Guideline for Athletic Banned Substances or the NFL/NFLPA Banned Substance List; However, soy lecithin may contain naturally occurring Isoflavones, which do have aromatase and selective estrogen receptor modulation activity. Section S4 of The WADA 2023 Prohibited List, effective January 1, 2023, states that "Selective Estrogen Receptor Modulators (SERMs), including but not limited to. . ." are prohibited. As this list is not specific, ADM can only state the soy lecithin products, which contain soy, do not have Hormone and Metabolic Modulators intentionally added nor used in the manufacturing process, specifically identified by the discrete chemical name on the above identified lists and not by a more general class of compounds.

Gluten

ADM Soy Lecithin products are defined as "gluten-free" under the Health and Human Services, Final Rule for FDA 21 CFR 101, Food Labeling; Gluten-Free Labeling of Foods. Lecithin ingredients are produced under 21CFR 101.91 as per the "Major Provisions of the Rule", for foods:

i.) Does not contain an ingredient that is gluten containing grain

ii.) Does not contain an ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten;

iii.) Or contain an ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 ppm or more gluten in the food ingredient

iv.) Or naturally does not contain gluten; and that any adventitious presence of gluten in the food ingredient is below 20 ppm gluten

According to the legal requirements related labelling under the regime established by Regulation (EU) No 1169/2011 on the provisions of food information to consumers our listed ingredients can be expected to be used in foodstuffs meeting these criteria for people who are intolerant to gluten in accordance with the implementing Regulation (EU) No 828/2014 which require that: Gluten-free foodstuffs must contain less than 20 mg/kg of gluten, in the food as sold to the final consumer. Note ADM does not test for gluten per lot.

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Microbial Risk

In general lecithin is a low microbial risk ingredient. Lecithin is produced at high temperatures in our vegetable oil refineries. Lecithin products have very low moisture content and, more importantly, very low water activity. Water activity in a food product or food ingredient can be related to the potential for microbial growth when the product is exposed to conditions that make microbial growth possible. Therefore, it is important that lecithin products be stored properly. Lecithin should always be stored in properly sealed containers that limit exposure to moisture.

ADM has complete HACCP plans in place at each of our production facilities and each facility is inspected and audited by ADM Quality Assurance personnel on a routine basis.

Pesticides and Residuals

ADM Lecithin products are monitored annually for pesticide residues. The analysis is performed by an accredited laboratory and to date, results have been below limit of quantification (LOQ). The results are in line with current FDA guidelines as well as European Regulation (EC) No 396/2005, including subsequent amendments, including Commission Regulation (EU) 2020/1085*

ADM Lecithin products are manufactured following U.S Food and Drug Administration Good Manufacturing Practice guidelines and are fit for human consumption. ADM Quality Control will continue the pesticide residue monitoring program as part of our overall Quality Management system to ensure a safe and wholesome food ingredient supply.

**Chlorates and chlorate compounds:* Chlorate is not intentionally added to ADM Soy Lecithin products. Chlorate levels present may result from drinking water use in process or chlorine disinfectant use on equipment. Some foods can show tendencies for chlorate accumulation which can cause higher chlorate presence. The use of chlorine disinfectants and chlorinated water that is used within the process, is in compliance with all local requirements and an eventual accumulation and chlorate presence is unavoidable. This is in compliance with Annex III, Regulation (EU) No. 396/2005 as no other chlorate contamination source is utilized in the process. ADM is monitoring through regular testing to keep the accumulation within the ALARA principle.

**Chlorpyrifos and Chlorpyrifos-methyl:* soy lecithin products are in compliance with Regulation (EU) No 396/2005 for Chlorpyrifos and Chlorpyrifos-methyl, test results show that presence is below limit of detection (LOD) of 0.01mg/kg, the defaulted MRL.

Proposition 65

ADM is familiar with the list of chemicals published pursuant to the California Safe Drinking Water and Toxic Enforcement Act of 1986, as amended, and the related regulations, which are generally known as Proposition 65. It is our opinion that Proposition 65 does not require any warning label for the products we sell you.

ADM Lecithin products are manufactured from a number of agricultural products where naturally occurring chemicals may be present. All agricultural products may from time to time contain one or more of the chemicals which have been listed under Proposition 65, allow, subject to certain conditions, naturally occurring chemicals be present in food products. See: Cal. Code Regs, Tit 27, Sec. 25501.

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Heavy Metals

Heavy metals, as listed below, are not added to ADM Soy Lecithin products during processing; however may be detected due to natural occurrence. Soy Lecithin products are tested annually and analysis to date have met the FCC XII limit of <1 mg/kg limit for lead. Detection limits for heavy metals are as listed below: [Method AOAC 2011.19 & 993.14 (modified), ICP Mass Spectrometry].

Heavy Metal	Typical Analysis
Arsenic	<0.02 mg/kg
Cadmium	<0.01 mg/kg
Lead	<0.02 mg/kg
Mercury	<0.01 mg/kg

Residual Solvents

ADM conducts per lot hexane solvent testing for the deoiled lecithin products. It is important to note that ADM Lecithin products are not sold as USP grade.

USP General Chapter <467> Residual Solvents defines residual solvents as organic volatile chemicals used or produced in the manufacture of drug substances or excipients, or in the preparation of drug products. Furthermore, this chapter states that it is only necessary to test for those solvents used in the production of, or resulting from the production of, the substance, excipients or products.

ADM's deoiled lecithin products are manufactured through processes which utilize hexane – the same solvent used to remove the crude soybean oil from the crushed soybeans. Therefore, only the Class 2 solvent hexane is likely to be present. Residual solvent testing to-date has shown the residual solvent level to be well below the 290 ppm maximum concentration as listed in <467> which would necessitate quantification and reporting.

ETO/Irradiation/Radioactivity

ADM Lecithin products have not been handled by, exposed to, or have been treated with irradiation. It is affirmed that the products are not sterilized using Irradiation or fumigation. These ingredients are not exposed to ionizing radiation or ethylene oxide (ETO) during the manufacturing process. No radiological, irradiation, nor ETO risks have been identified by the Food Safety Team for the ADM Ultralec® products.

Source Material

ADM Deoiled Soy Lecithin products are produced in the United States. In addition, the raw materials used in the manufacture of standard soy lecithin products are of United States or Canadian origin. The scientific name for soybeans used in the production of ADM Soy Lecithin products is *Glycine max*.

Composition

Soy Lecithin - 100%

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Ready to Eat (RTE)

The Food and Drug Administration (FDA) defines a ready-to-eat (RTE) food in 21 CFR 117.3 as "any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards."

ADM is not passing on any hazards that require a preventative control. However, following the guidelines laid out by the Food Safety Modernization Act (FSMA), Ultralec® products are not considered a RTE food since ADM markets and labels it as a business to business product, and it is not considered readily foreseeable that Ultralec® products will be consumed without further processing. ADM therefore recommends you conduct a risk assessment of the ingredient and determine if additional processing is required, by you the customer, in order to use for your finished RTE application.

Miscellaneous Exclusionary Statement

ADM Ultralec® products are produced following the U.S. Food and Drug Administration current Good Manufacturing Practice guidelines. The following compounds are not knowingly introduced directly or through processing aids during production, storage, or shipment. These compounds are not expected to be present, and therefore are not specifically tested for presence or absence.

- Additives
- Animal Products
- Animal By-products
- Animal derived products
- Antibiotics
- Dyes
- Enzymes
- Ethylene Oxide (ETO)
- Irradiation/Radioactivity
- (Iso)paraffin, mineral oil, petrolatum
- Latex
- Melamine (or cyanuric acid)
- Monosodium Glutamate
- Nanotechnology
- Nitrosamines
- Paraben or Paraben-related compounds
- Phenylalanine
- Phthalates
- Perfluorinated Compounds (PFCs)
- Preservatives
- Partially Hydrogenated Oils / Trans Fats
- Sewage and Sludge
- Sulfates

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Food Safety & Quality Information

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Letter of Guarantee

ADM hereby warrants and guarantees that the above listed product sold to you has been approved by the US Food and Drug Administration for their use in foods or are Generally Recognized As Safe (GRAS), or exempt from the provisions of the 1958 Additives Amendment to the Federal Food, Drug and Cosmetic Act, and are allowed for sale in Canada.

We further guarantee that none of the foregoing products comprising any shipment or other delivery now in transit or hereafter made to you is, as of the date of shipment or delivery, adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act or any practically similar state or municipal law, or is an article which many not under Section 404 or 505 of said Act, be introduced into interstate commerce. All of the foregoing is a continuing guarantee, subject to revocation upon written notice.

FDA Bioterrorism Registration

ADM facilities that manufacture, process, pack, or hold Ultralec® products or facilities within our distribution network are fully compliant with this registration requirement. The US Public Health Security and Bioterrorism Preparedness Response Act of 2002 requires registration with the US Food and Drug Administration of facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. The 2010 Food Safety Modernization Act requires a re-registration of these facilities prior to December 31, 2010 and biennially thereafter.

Food Safety Modernization Act (FSMA) Compliance

Food Safety Modernization Act (FSMA) compliance dates for the following programs are in affect for ADM. ADM has enacted programs to comply with the requirements.

- Preventative Controls for Human Food
- Preventative Controls for Animal Food
- Reportable Food Registry Notification (RFR)
- Sanitary Transportation Guidelines
- Foreign Supplier Verification

Current Good Manufacturing Practices and GFSI

ADM certifies that this product is manufactured following current Good Manufacturing Practices (cGMP) as defined by FDA 21 CFR Part 117. Our programs have been audited and are currently SQF certified. Our quality program includes, but is not limited to the following procedures and guidelines.

- Allergen Control
- Auditing Procedures
- Calibration Procedures
- CAPA Program
- cGMP Requirements
- Chemical Control Program
- Cleaning Procedures
- Glass, Brittles, & Plastic Program
- Food Safety Plan / HACCP
- In-Process Controls
- Incoming Good Requirements
- Internal Auditing
- Isolation of Rejected Materials
- Issuance of Certificate of Analysis
- Issuance of Product Specifications
- Laboratory Technician Training
- Management of Change
- Master Manufacturing Plan
- Out-of-Specification Handling
- Outsourced Services
- Personnel Training
- Pest Control
- Pre-requisite Programs
- Preventative Maintenance
- Product Withdrawal and Recall
- Recording of Sampling Data
- Records Retention
- Release of Finish Goods
- Retain Samples
- Significant Change Notification
- Site Security
- Specification Requirements Review
- Supplier Management
- Traceability & Mock Recall

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Food Safety & Quality Information

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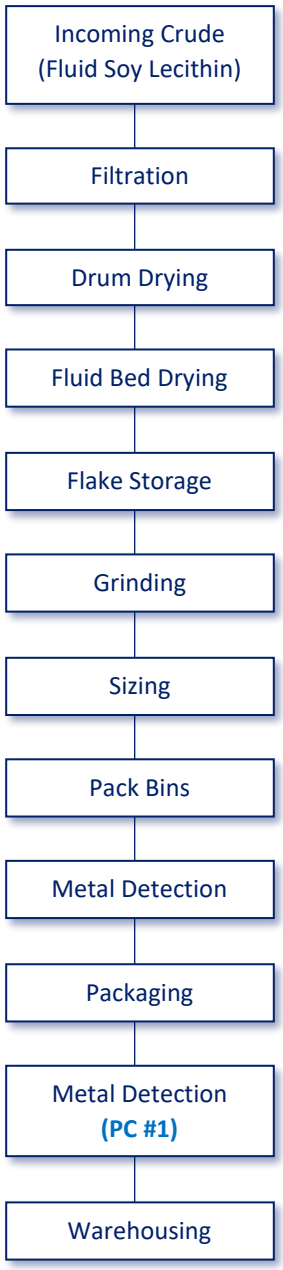
HACCP Summary and Flow Diagram

Food Safety Plans are an integral piece of our quality and food safety systems. Ultralec® De-oiled Soy Lecithin products are produced at the Decatur, IL De-oiled manufacturing facility. A cross-functional team of colleagues have reviewed annually, at a minimum, manufacturing hazard analysis and risk assessments to ensure accuracy and adequacy.



Biological Risk Summary

De-oiled Lecithin is a low moisture product that is processed under conditions that are not favorable for microbiological growth. All lots of De-oiled Lecithin are tested for microbiological growth prior to release.

Physical Risk Summary

De-oiled Lecithin products are produced in closed and dedicated equipment so physical hazards are not generally associated with the product. A simplified process flow diagram showing the major processing steps and Preventative controls is shown to the right. Filters, screens, magnets, and metal detectors are used at various stages to minimize the potential for physical contamination.

The final metal detector **(PC #1)** sensitivities are set to detect:

3.5mm Stainless Steel
3.5mm Ferrous, and
3.5mm non-Ferrous

Chemical Risk Summary

Ingredients used in the manufacture of De-oiled soy lecithin products are subjected to a risk analysis. Chemical hazards are evaluated from the inputs into the process. All materials are Food Grade and restricted from direct contact where applicable. Hexane is used in the manufacturing process. Hexane residuals are removed during processing and are monitored through contaminant testing.

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Social Programs

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US National Bioengineered Food Disclosure Statement

On December 21, 2018, the Agricultural Marketing Service, USDA released the final rule establishing the new mandatory National Bioengineered Food Disclosure Standard (NBFDS). The NBFDS requires food manufacturers, importers, and other entities that label foods for retail sale to disclose information about bioengineered (BE) food and BE food ingredients. This rule is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods. This rule is effective from February 19, 2019 with an implementation date of January 1, 2020. The mandatory compliance date for BE labeling began January 1, 2022.

ADM Soy Lecithin product may be derived from bioengineered crops. The process for deoiled Lecithin was validated through testing and strict documentation. Based on the commercial availability of seed, samples of seed and refined end-product lecithin have gone through qualitative PCR testing. In the validation, it was shown that qualitative PCR test results were positive for seed. However all highly refined soy lecithin samples tested negative. Based on ADM's interpretation of the USDA AMS NBFDS, the validation testing data, historical testing data as well as our knowledge and experience with the process, ADM Deoiled Soy Lecithin products will not require disclosure under the National Bioengineered Disclosure Standard.

This highly refined food ingredient, produced at ADM manufacturing facilities, has been purified through a multi-step process that will remove protein, DNA, and other impurities. Testing for the presence of recombinant DNA using PCR analysis on highly refined oils has repeatedly shown non-detectable limits (0.01% limit of detection) for all common markers for bioengineered soy products.

Natural Classification

There is no formal US FDA definition for the term "natural" except as it is defined for "natural flavors" under 21 CFR 101.22. The Lecithin ingredients do not fit the definition of "flavor". Additionally, the FDA is not restricting the use of the term "natural" excepts as it applies to 21 CFR 101.22. In an advisory opinion the FDA has stated that it had not objected to the use of the term natural if "the food des not contain added color, artificial flavors or synthetic substances". The USDA has established a working definition of the term "natural" as "a product containing no artificial ingredient or added color and is only minimally processed".

ADM lecithin is produced by solvent extraction of crude soy oil from soybeans, followed by hydration of the soy gums and subsequent drying. It may or may not be bleached to obtain a finished product color depending upon customer requirements. ADM does not add color, artificial flavors or synthetic substances to the finished goods. Final label claims for your product should be reviewed by your legal counsel and are not the responsibility of ADM.

Organic Classification

ADM Soy Lecithin products are not organic certified.

SEDEX

ADM WFSI- Specialty Ingredients Decatur West Plant has been audited on the basis of the Supplier Ethical Data Exchange (SEDEX). In this audit, an approved auditing firm verifies to what extent suppliers assume their social responsibility and satisfy general ethical principals in the fields of health care, employee rights, job security, job satisfaction and environmental protection. The ADM West plant in Decatur, IL SEDEX registration number is ZS1059474.

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Social Programs

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Sustainability

ADM believes there is a direct relationship between the health of the planet and our natural resources, and the health of our business and communities in which we operate. More and more, consumers around the world expect their food and drink to come from sustainable ingredients, produced by companies they trust. ADM has a complete sustainability website to share our vision, actions, and accomplishments: https://www.adm.com/sustainability.

Vegan / Vegetarian

ADM Lecithin products, or any ingredients used in the manufacturing of these products, do not contain any components of animal origin. All processing equipment used in the manufacturing of ADM Lecithin is dedicated to lecithin production only and has no contact with ingredients of animal origin. The packaging components do not contain ingredients of animal origin as well. ADM Lecithin products are considered suitable for vegans.