

# **Technical Information**

# Yelkin<sup>®</sup> TS Lecithin

Product Code 700160

#### **Product Description**

Yelkin® TS lecithin is a surface-active agent with unique properties, derived from soybeans. Yelkin® TS lecithin can modify the boundary layers between many types of substances. In the presence of two immiscible liquid phases, Yelkin® TS lecithin reduces the surface tension and acts as an emulsifier. When used between a solid and a liquid phase (instantizing) Yelkin® TS lecithin acts as a wetting and dispersing agent. When used between solid phases Yelkin® TS as a lubricant or release agent.

#### **Applications**

Lecithin has been found useful in a wide variety of food processing applications. As a food emulsifier lecithin is used in the manufacture of margarine and vegetable or dairy based milk replacers including infant formula and ready to use frostings. Lecithin is the active ingredient in many food grade release agents such as pan oils, griddle greases and aerosol coatings. Lecithin is also used to alter viscosity in chocolate products and compound coatings. In bread baking applications, lecithin acts to improve dough machinability, volume, symmetry and shelf life. In crackers, cookies, pastry, cakes and pies lecithin improves shortening dispersion and acts as a release agent.

#### **Specification**

<u>Limit</u>	Method
62.0	AOCS
30	AOCS
1.0	AOCS
0.05	AOCS
100	AOCS
17	AOCS
3,000	FDA/BAM
50	FDA/BAM
50	FDA/BAM
Negative	FDA/BAM
Negative	FDA/BAM
	62.0 30 1.0 0.05 100 17 3,000 50 50 Negative

### **Other Information**

**Ingredient Statement** Soy Lecithin

#### **Regulatory Information**

Country of Origin: United States and/or Canada Lecithin GRAS: 21 CFR 184.1400 Lecithin EU Food additive number: E322 CAS#: 8030-76-0

#### **Social Suitability**

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

#### **Available Pack Size**

205 kg net weight drums (700160-EL) Bulk Trucks (700160-00) 40 lb net weight pail (700160-B4) 1 Metric ton totes (700160-1E)

#### Other

HLB – Approx. 4



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# Storage and Shelf Life

Storage temperatures should be between 50-95°F (10-35°C). Exposure to freezing or near-freezing temperatures may promote separation of oil from the phospholipids. Separated product may be remixed under heat and agitation without loss of functionality. Avoid excessive exposure to light and moisture. Shelf life is a minimum of 36 months when stored unopened in the original packaging.

#### **Lot Coding**

0		
Lot code: Y	(MMDDPBBB	Example: 240101P001
YY	2-digit year code	This lot is the first batch packed on January 1, 2024 at the Decatur, IL
MM	2-digit month code	Phospholipid facility.
DD	2-digit day code	
Р	*Facility identifier Code	
BBB	sequential batch of the day	
	*Facility identifier Codes	
	Q = Quincy, IL	
	P = Phospholipids – Decatur	
	E = East Plant – Decatur	
	L = Lincoln, NE	
	D = Des Moines, IA	
	W = Windsor, ON	

#### Packaging

Packaging is in 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".



# **Typical Nutrition Information**

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Nutrient	/100g		
Total Calories, kcal*	790		
Calories from Fat	650		
Calories from Saturated Fat	130		
Total Fat*	72.1 g		
Saturated Fat**	13.8 g		
Stearic***	3.1 g		
Palmitic***	9.8 g		
Trans Fat**	0.2 g		
Polyunsaturated Fat**	44.0 g		
Linoleic [ω-6]	38.7 g		
α-linolenic [ω-3]	5.2 g		
Monounsaturated Fat**	11.0 g		
Oleic***	10.7 g		
Cholesterol	0 mg		
Sodium	7.4 mg		
Potassium	1050 mg		
Total Carbohydrate	3.7 g		
Dietary Fiber	0 g		
Sugars	2.1 g		
Added Sugars	0 g		
Protein	Trace		
Vitamin D	0 mg		
Vitamin A	0 IU		
Vitamin C	0 mg		
Calcium	26.1 mg		
Iron	0.4 mg		
Phosphorus	2180 mg		
Vitamin E	18.2 IU		
*Total Fat is reported as grams	of Triglyceride		

Other	/100g
Moisture***	0.3 g
Total Ash (includes Calcium,	9.6 g
Iron and Phosphorus)***	
Total Lipidic Material <sup>+</sup>	86.4 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	15			
Phosphatidylethanolamine	13			
Phosphatidylinositol	9			
Phosphatic Acid	4			
Choline (%)****	2			
**** 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
Mollusca 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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#### **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 potentially contain naturally occurring isoflavones, which do have aromatase and selective estrogen receptor modulation activity. Section S4 of The WADA 2024 Prohibited List, effective January 1, 2024, 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 ADM Soy Lecithin products 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 Status**

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 provision 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.

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

Yelkin<sup>®</sup> products do not contain and are not processed, stored, packaged, or delivered with any animal products, by-products, or animal derived products

#### **ETO/Irradiation/Radioactivity**

ADM Yelkin<sup>®</sup> 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 Teams for the sites that manufacture the ADM Yelkin<sup>®</sup> products.



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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<sup>\*</sup>.

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. 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.

\**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**

As of the date of the issuance of this document, to the best of our knowledge, the above named product is not reasonably believed to contain substances known to the State of California under Proposition 65 to cause cancer or reproductive toxicity. Proposition 65 listed substances have not been intentionally added to our finished product, nor is the manufacturing process known or expected to produce listed substances.

Please note that it is the duty and obligation of the end manufacturer to evaluate its final product to ensure that it is in compliance with all applicable laws and regulations, including but not limited to California Proposition 65. ADM cannot and does not guarantee that downstream products subject to further processing, formulating or conditions of use are in compliance with all laws and regulations. It is best practice to test your final product for Proposition 65 listed chemicals as there may be other sources of these chemicals in your downstream formulation, packaging, or manufacturing process unrelated to ADM product(s).



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#### **Residual Solvents**

Based on historical testing in which results have indicated very low levels of residual solvents, ADM fluid lecithin products are analyzed annually. 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 fluid 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.

#### **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. Analyses to date have met the FCC limit of <1 mg/kg limit for lead, note ADM does not claim compliance to the FCC standard. Detection limits for heavy metals are as listed below: [Method AOAC, 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

#### **Source Material**

ADM Soy Lecithin products are produced in the United States and /or Canada. 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), Yelkin® 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 Yelkin® 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 Yelkin® 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 •

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- Ethylene Oxide (ETO)
- **Animal Products** •
- Irradiation/Radioactivity (Iso)paraffin, petrolatum
  - •
- Antibiotics Artificial flavors
- Dyes / Artificial colors

Animal By-products

Animal derived products

- Enzymes
- Latex
- Melamine (or cyanuric acid)
- Monosodium Glutamate
- Nanotechnology
- Nitrosamines

- Paraben or Paraben-related compounds
- Partially Hydrogenated Oils / Trans Fats •
- Perfluorinated Compounds (PFCs) •
- Phenylalanine
- Phthalates •
- Preservatives
- Sewage and Sludge
- Sulfates



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# Food Safety & Quality Information

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 the USA and 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 Yelkin<sup>®</sup> 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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#### **HACCP Summary and Flow Diagram**

Food Safety Plans are an integral piece of our quality and food safety systems. Yelkin® products are produced at the Decatur, IL, Des Moines, IA, Windsor, ON, Quincy, IL, and Lincoln, NE manufacturing facilities. 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**

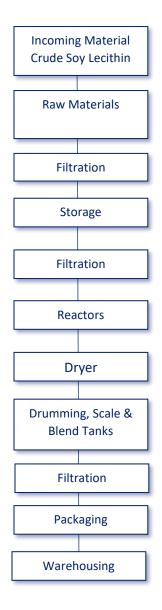
Fluid Soy Lecithin is a low moisture product that is processed under conditions that are not favorable for microbiological growth. All lots of Fluid Soy Lecithin with the exception of industrial lecithin are tested for microbiological growth prior to release.

#### **Physical Risk Summary**

Fluid Lecithin products are produced in a closed and dedicated system so physical hazards are not generally associated with the product. A simplified process flow diagram showing the major processing steps is shown to the right. 50 micron filters are used at various stages to minimize the potential for physical contamination.

#### **Chemical Risk Summary**

Ingredients used in the manufacture of fluid lecithin products are subjected to a risk assessment. 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. The mandatory compliance date for BE labeling began January 1, 2022.

ADM Soy Lecithin product may be derived from bioengineered crops. This highly refined food ingredient, produced at ADM plants 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).

ADM has conducted the validation of the processing system by testing incoming seeds and the finished product going through the documented refining process.

As expected, qualitative PCR test results were positive for seed. All highly refined liquid 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 Soy Lecithin products will not require disclosure under the National Bioengineered Disclosure Standard.

#### **Natural Classification**

The United States Food and Drug Administration (FDA) does not explicitly define "natural" or govern the term's use. In an advisory opinion the FDA has stated that is has not objected to the use of the term natural if "the food does 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 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. 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.

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#### **SEDEX**

ADM soy lecithin manufacturing facilities have 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. SEDEX registration numbers for the locations that manufacture this product are:

ADM West Plant - SEDEX Registration number ZS1059474 ADM Lincoln – SEDEX Registration number ZS1001297 ADM Des Moines - SEDEX Registration number ZS1053930 ADM Quincy - SEDEX Registration number ZS1026366 ADM Agri-Industries Ontario – SEDEX Registration number ZS1070570 ADM East Plant – SEDEX Registration number ZS1029072

#### 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 Soy Lecithin products are considered suitable for vegetarian and vegan diet. ADM Soy Lecithin products and all materials used in the manufacturing of these products, do not contain any components of animal origin. All processing equipment used in the manufacturing of ADM soy lecithin is dedicated and has no contact with ingredients of animal origin. The packaging components do not contain ingredients of animal origin.