

PRODUCT REGULATORY SUMMARY

Linsorb 80 FGK

DATE: 04/09/2021

INCI

POLYSORBATE 80

COMPOSITION

97% Polyoxyethylene (20) Sorbitan Monolaurate (CAS No. 9005-65-6)

3% Water (CAS No. 7732-18-5)

ALLERGENS

Linsorb 80 FGK is not produced using nor expected to contain any of the 26 fragrance allergens listed in Annex III of Regulation (EC) No 1223/2009.

Additionally, Linsorb 80 FGK is not produced using nor expected to contain any of the common allergens listed below in accordance with Regulation (EU) No. 1169/2011 and the FDA Food Allergens Guidance.

- Cereals containing gluten and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and products thereof
- Tree nuts (walnuts, pecans, etc.) and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxides and sulfites

ANIMAL CONTENT

The origin and source or the raw materials used in the production of Linsorb 80 FGK are entirely natural. This product does not contain any raw materials produced from or derived from animal origin. The manufacturing process does not use any ingredient or animal origin nor is the product expected to come into contact with animal products during storage and transportation.

Therefore, we consider Linsorb 80 FGK to be free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

ANIMAL TESTING

Barentz North America LLC does not perform, contract, or participate in animal testing with any of our products. Additionally, Linsorb 80 FGK has not been tested on animals by the manufacturer of this product.

COUNTRY OF ORIGIN

Linsorb 80 FGK is produced in Mexico. Therefore, this product does not qualify for the United-States-Mexico-Canada Agreement (USMCA).

CARCINOGENS, MUTAGENS, TOXIC FOR REPRODUCTION (CMR)

Linsorb 80 FGK is not expected to contain any carcinogens, mutagens, or toxic for reproduction (CMR) substances outlined within Annex II of Council Directive 76/769/EEC.

FEEDSTOCK ORIGIN

Linsorb 80 FGK is produced from sorbitol, fatty acid and ethylene oxide, using conventional chemical technology without the use of biotechnological means. The manufacturing process for Linsorb 80 FGK includes synthesis, refining and purification.

FDA STATUS

Barentz North America LLC is registered with the United States FDA and is therefore subject to unannounced FDA compliance inspections.

FOOD GRADE

Linsorb 80 FGK meets the USP/NF FCC current requirements and complies with the uses allowed in the U.S. Code of Federal Regulation 21 CFR sections described below:

Direct Food Additives

- 21 CFR 172.515 – Synthetic flavoring substances and adjuvants
- 21 CFR 172.840 – Polysorbate 80
- 21 CFR 173.340 – Defoaming Agents

Indirect Food Additives

- 21 CFR 175.105 – Adhesives
- 21 CFR 178.3400 – Emulsifiers and/or surface-active agents

A copy of the manufacturer's current ISO 9001 Quality Management System Standards certificate and BRCs Global Standard for Food Safety certificate available upon request.

GLUTEN

Linsorb 80 FGK does not contain nor is it expected to come into contact with gluten or products containing gluten.

GLOBAL INVENTORY

To the best of our knowledge, Linsorb 80 FGK is either exempt from or can be found as a positive listing on the chemical inventories listed below.

- Australia— Australian Inventory of Chemical Substances (AICS)
- Canada — Domestic Substances List (DSL)
- China — Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)
- New Zealand— New Zealand Inventory (NZIoC)
- The Philippines— Philippine Inventory of Chemicals and Chemical Substances (PICCS)
- United States— Toxic Substances Control Act Inventory (TSCA)

GENETICALLY MODIFIED ORGANISMS (GMO)

Linsorb 80 FGK is produced from sorbitol, fatty acid and ethylene oxide, using conventional chemical technology without the use of biotechnological means. However, the chemical raw material, Sorbitol, used in the manufacturing process is made by hydrogenation of starch hydrolysates from corn that can be derived from Genetically Engineered Corns.

It is important to emphasize that both the process for the production of our raw materials, as well as, our final product is manufactured (from synthesis, refining, and to purification) that, to the best of our knowledge, do not leave residues of protein or DNA from the genetic modification of the original crops.

HALAL

Current certificate available upon request.

HEAVY METALS & ELEMENTAL IMPURITIES

None of the toxic elements—Cadmium, Hexavalent Chromium, Lead, or Mercury—are used as raw materials nor deliberately added during the manufacturing process of the product. With this in mind, Linsorb 80 FGK is expected to be free from the above-mentioned toxic elements. Any incidental amount would be expected to be less than 100 parts per million (ppm).

KOSHER

Current certificate available upon request.

MELAMINE

Linsorb 80 FGK is not a source for protein, therefore Linsorb 80 FGK should not be considered “at risk” for intentional adulteration with melamine. Melamine is not present as an ingredient, sub-ingredient, processing, or present on a production line at the manufacturing facility.

NUTRITION FACTS

Per 100 grams

Calories (kcal)	535
Total Fat (g)	28.79 As Fatty Acids
Saturated Fat (g)	2.49 As Fatty Acids
Polyunsaturated Fat (g)	0.06 As Fatty Acids
Monounsaturated Fat (g)	26.24 As Fatty Acids
Trans Fat (g)	0.42
Total Carbohydrates (g)	68.89
Dietary Fiber (g)	0
Total Sugar (g)	0
Added Sugars (g)	0
Protein (g)	0
Cholesterol (mg)	<0.01
Sodium (mg)	10.185
Calcium (mg)	<0.1
Iron (mg)	0
Potassium (mg)	<0.5
Vitamin D (mcg)	0

PESTICIDE

While Linsorb 80 FGK is not routinely tested for pesticides or aflatoxins, based upon knowledge of the manufacturing process and handling of raw materials and finished products, pesticide and aflatoxin contamination is not considered a risk in Linsorb 80 FGK.

PROPOSITION 65

Linsorb 80 FGK contains the following ingredients known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act"

- *Ethylene Oxide*: 1 ppm max.
- *1,4 Dioxane*: 10 ppm max.

PHTHALATES

Linsorb 80 FGK and packaging used for this product is not manufactured using phthalates and does not contain phthalates, including, but not limited to, DEHP, DINP, DNOP, DIDP, DBP, and BBP.

REACH REGULATION (EC) No 1907/2006

Linsorb 80 FGK has been duly registered by an appointed Only Representative in the European Union in accordance with REACH regulations (EC) 1907/2006.

RSPO STATUS

While the manufacturer of Linsorb 80 FGK and Barentz North America LLC are members of the Roundtable on Sustainable Palm Oil (RSPO), the palm used in the production of Linsorb 80 FGK is not RSPO certified.

RSPO grade of this product is available—contact your Barentz account manager for more information.

SUBSTANCES OF VERY HIGH CONCERN (SVHC)

None of the substances contained in the Candidate List of Substances of Very High Concern (SVHC) as of January 19, 2021 are intentionally used nor added in the manufacture of Linsorb 80 FGK.

Because the presence of the substances in the Candidate List are not expected under normal conditions, the absence has not been checked by tests.

VEGAN

Because Linsorb 80 FGK is manufactured without the use of any ingredients of animal origin, it is considered vegan friendly.

DISCLAIMER

The information contained in this document is based upon data obtained from the manufacturer. This information is offered only as a guide to the handling of this specific material and conditions. The use and handling of this material may require alternate and additional considerations. No representation or warranty of any kind whatsoever is given or implied by Barentz North America LLC with respect to any information contained herein. In no event or circumstance shall Barentz North America LLC be liable for any damages, losses, liabilities or injuries of any kind whatsoever arising from any information contained herein including, without limitation, all indirect, special or consequential damages or losses which may result from the information contained herein.