

## PRODUCT REGULATORY SUMMARY

# Sunflower Oil Mid-Oleic K

MANUFACTURER: CATANIA OILS

DATE: 04/09/2021

**INCI**

Helianthus annuus (Sunflower) Seed Oil

**COMPOSITION**

100% Sunflower Seed Oil (CAS No. 8001-21-6).

**ALLERGENS**

Sunflower Seed Oil Mid-Oleic K 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, this product is not produced using nor expected to contain any of the common allergens listed below.

- 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
- Wheat
- Buckwheat
- Animal derivatives

**ANIMAL CONTENT**

The origin and source or the raw materials used in the production of Sunflower Seed Oil Mid-Oleic K are entirely botanical or manufactured. 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 Sunflower Seed Oil Mid-Oleic K 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, Sunflower Seed Oil Mid-Oleic K has not been tested on animals by the manufacturer of this product.

## **COUNTRY OF ORIGIN**

Sunflower Seed Oil Mid-Oleic K is manufactured in the United States of America at the below address.

Catania Oils  
3 Nemco Way  
Ayer, MA 01432-0227 USA

## **CARCINOGENS, MUTAGENS, TOXIC FOR REPRODUCTION (CMR)**

Sunflower Seed Oil Mid-Oleic K 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**

Sunflower Seed Oil Mid-Oleic K is manufactured using plant material. The oil is extracted from the seed kernel of the Helianthus annuus plant using a chemical solvent. The oil is refined, bleached, winterized, and deodorized.

## **FDA STATUS**

Barentz North America LLC is registered with the United States FDA and is therefore subject to unannounced FDA compliance inspections. Additionally, the manufacturer of Sunflower Seed Oil Mid-Oleic K, Catania Oils, is also registered with the FDA.

## **FOOD GRADE**

Sunflower Seed Oil Mid-Oleic K is Generally Recognized as Safe (GRAS) per 21 CFR §182.1. This product is manufactured using Good Manufacturing Practices and is safe for its intended use in foods.

## **GLUTEN**

Sunflower Seed Oil Mid-Oleic K 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, Sunflower Seed Oil Mid-Oleic K, with CAS number 8001-21-6, 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)
- South Korea— Korean Existing Chemicals List (KECI)
- Taiwan— Taiwan Chemical Substance Inventory (TCSI)
- United States— Toxic Substances Control Act Inventory (TSCA)

## **GENETICALLY MODIFIED ORGANISMS (GMO)**

Sunflower Seed Oil Mid-Oleic K is not manufactured using genetically modified organisms and the manufacturing process does not use raw materials or processing aids containing or derived from genetically modified material.

Therefore, Sunflower Seed Oil Mid-Oleic K should be considered non-Genetically Modified (nGMO).

## **HALAL**

While Sunflower Seed Oil Mid-Oleic K is not certified to be Halal, we believe it to be compliant with Halal regulations.

## **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, Sunflower Seed Oil Mid-Oleic K 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.

## **LOT CODE**

Sunflower Seed Oil Mid-Oleic K is assigned a product lot code sequentially at the time of receipt or blending. A seven-digit numeric lot number is assigned automatically within the manufacturer's ERP system.

## MELAMINE

Sunflower Seed Oil Mid-Oleic K is not a source for protein, therefore Sunflower Seed Oil Mid-Oleic K should not be considered "at risk" for intentional adulteration with melamine.

## NANOMATERIAL

The use of nanomaterials or nanotechnology is not utilized during the manufacture of Sunflower Seed Oil Mid-Oleic K.

## NUTRITION FACTS

\*Per 100 grams

Total Fat (g)	100
Saturated Fat (g)	9
Trans Fat (g)	1
Cholesterol	Not a dietary source
Total Carbohydrates (Digestible by difference)	Not a dietary source
Dietary Fiber	Not a dietary source
Added Sugars	Not a dietary source
Protein	Not a dietary source
Vitamin E (mg)	41.08
Vitamin D	Not a dietary source
Calcium	Not a dietary source
Iron	Not a dietary source
Potassium	Not a dietary source
Sodium	Not a dietary source
Calories	900

1. The above values should be considered typical nutritional values. Refer to the Certificate of Analysis for applicable lot specific analytical values.

## **PESTICIDE**

Sunflower Seed Oil Mid-Oleic K is routinely tested to confirm absence of pesticide residue. There have been no detected levels of Organophosphate and Organochlorinated residuals in routine testing.

## **PROPOSITION 65**

Sunflower Seed Oil Mid-Oleic K is not expected to contain any substances known to the State of California to cause cancer, birth defects, or other reproductive harm, at levels which would require a warning under California Proposition 65, Safe Drinking Water and Toxic Enforcement Act of 1986 as of December 18, 2020.

## **PHTHALATES**

Sunflower Seed Oil Mid-Oleic K 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.

## **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 Sunflower Seed Oil Mid-Oleic K. Because the presence of the substances in the Candidate List are not expected under normal conditions, the absence has not been checked by tests.

## **RESIDUAL SOLVENTS & IMPURITIES**

Organic solvents are not used during the manufacture of Sunflower Seed Oil Mid-Oleic K. Based upon a knowledge of the raw materials, manufacturing and controlled handling, shipping and storage of Sunflower Seed Oil Mid-Oleic K, we believe there is not a significant potential for ICH Q3C Class 1, Class 2, or Class 3 solvents, or any other organic solvents to be present.

## **VEGAN**

Because Sunflower Seed Oil Mid-Oleic K 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.