

## PRODUCT REGULATORY SUMMARY

# Magnesium Sulfate Anhydrous

MANUFACTURER: AVANTOR

DATE: 04/09/2021

### COMPOSITION

≥ 99% Magnesium Sulfate Anhydrous (CAS No. 7487-88-9)

### ALLERGENS

Magnesium Sulfate Anhydrous 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, Magnesium Sulfate Anhydrous 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
- Sesame seeds and products thereof
- Sulfur dioxide and sulfites
- Lupin and products thereof
- Mollusks and products thereof
- Artificial flavors
- Monosodium glutamate
- Wheat
- Buckwheat
- Animal derivatives
- Artificial colors
- Safflower
- Sesame
- Sunflower
- Cottonseed
- Poppyseed
- Rice
- Gelatin
- Soy
- Yeast

Magnesium Sulfate Anhydrous is manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination with any other products or allergens.

## **ANIMAL CONTENT**

The origin and source or the raw materials used in the production of Magnesium Sulfate Anhydrous are entirely synthetic 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 Magnesium Sulfate Anhydrous 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, Magnesium Sulfate Anhydrous has not been tested on animals by the manufacturer of this product.

## **COUNTRY OF ORIGIN**

Magnesium Sulfate Anhydrous is manufactured in the United States of America at the below address.

Avantor  
600 Broad Street  
Phillipsburg, NJ 08865 USA

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

Magnesium Sulfate Anhydrous 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**

Magnesium Sulfate Anhydrous is manufactured by chemical synthesis and should be considered synthetic chemical material.

## **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 Magnesium Sulfate Anhydrous, Avantor, is also registered with the FDA.

## **GLUTEN**

Magnesium Sulfate Anhydrous 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, Magnesium Sulfate Anhydrous, with CAS number 7487-88-9, 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)**

Magnesium Sulfate Anhydrous 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, Magnesium Sulfate Anhydrous should be considered non-Genetically Modified (nGMO).

## **GRAS STATUS**

The United States Food and Drug Administration (FDA) has acknowledged Magnesium Sulfate Anhydrous as a Generally Recognized as Safe (GRAS) substance per 21 CFR §184.1443. This product is manufactured using Good Manufacturing Practices and is safe for use in foods.

## **HALAL**

While Magnesium Sulfate Anhydrous is not certified to be Halal, we believe it to be compliant with Halal regulations. The origin and source of the raw materials used for production of this product is synthetic. No vegetable or animal source raw materials are used. This product does not contain any derivative from milk, milk products, cereals, pulse, grapes, or animals.

## **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, Magnesium Sulfate Anhydrous 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**

Magnesium Sulfate Anhydrous displays a 10-digit batch number on the container label. Batch numbers are generated by SAP numbering system. Each batch is assigned a sequential, non-repeating batch number. The number does not contain any encoded data or plant information.

## **MELAMINE**

Magnesium Sulfate Anhydrous is not a source for protein, therefore Magnesium Sulfate Anhydrous 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 Magnesium Sulfate Anhydrous.

## **NITROSAMINES**

Nitrosamine and related compounds are not likely to be present in Magnesium Sulfate Anhydrous. Because the low potential for the presence of nitrosamines in this product, no specific testing was or is intended to be performed.

## **NUTRITION FACTS**

Bulk food chemicals that are intended for the use in manufacturing of finished food products or for products that are to be processed, labeled, or repackaged at a site other than where it is originally processed or packaged are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements 21 CFR §101.9(j)(9).

## **PESTICIDE**

Magnesium Sulfate Anhydrous is not routinely tested for pesticides or aflatoxins. None of the raw materials used are agricultural products nor are they treated with pesticides. With this in mind, pesticide and aflatoxin contamination is not considered a risk in Magnesium Sulfate Anhydrous.

## **PROPOSITION 65**

Magnesium Sulfate Anhydrous 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**

Magnesium Sulfate Anhydrous 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 Magnesium Sulfate Anhydrous. 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 Magnesium Sulfate Anhydrous. Based upon a knowledge of the raw materials, manufacturing and controlled handling, shipping and storage of Magnesium Sulfate Anhydrous, 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 Magnesium Sulfate Anhydrous 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.