

PRODUCT REGULATORY SUMMARY

Magnesium Sulfate Dried USP

MANUFACTURER: JOST CHEMICAL

DATE: 04/09/2021

COMPOSITION

100% Magnesium Sulfate Dried (CAS No. 7487-88-9)

ALLERGENS

Magnesium Sulfate Dried USP 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 Dried USP 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 Dried USP 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 Dried USP 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 Dried USP 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 Dried USP has not been tested on animals by the manufacturer of this product.

COUNTRY OF ORIGIN

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

Jost Chemical
8190 Lackland Road
St. Louis, Missouri 63114 USA

CARCINOGENS, MUTAGENS, TOXIC FOR REPRODUCTION (CMR)

Magnesium Sulfate Dried USP 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 Dried USP 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 Dried USP, Jost Chemical, is also registered with the FDA.

FOOD GRADE

Magnesium Sulfate Dried USP is considered food grade given that it is manufactured according to the principles and requirements of cGMPs and meets its defined microbiological requirements listed on the applicable Certificate of Analysis (COA).

GENETICALLY MODIFIED ORGANISMS (GMO)

Magnesium Sulfate Dried USP 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).

GLUTEN

Magnesium Sulfate Dried USP 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 Dried USP, 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)

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, Magnesium Sulfate Dried USP 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

First four digits = product and grade

Fifth digit = last digit of production year

Sixth, seventh, and eighth digits = consecutive lot produced in year indicated

Example: Lot 38041018

3804 = Product Code

1 = product produced in 2021

018 = the eighteenth lot of product code 3804 produced in 2021

MELAMINE

Magnesium Sulfate Dried USP 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 Dried USP.

NITROSAMINES

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

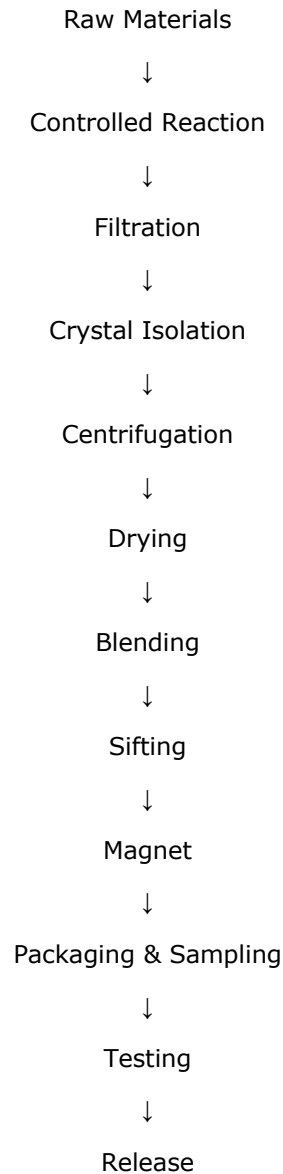
NUTRITION FACTS

Total Fat	Not a dietary source
Saturated Fat	Not a dietary source
Trans Fat	Not a dietary source
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 A	Not a dietary source
Thiamin	Not a dietary source
Riboflavin	Not a dietary source
Niacin	Not a dietary source
Vitamin C	Not a dietary source
Vitamin D	Not a dietary source
Calcium	Not a dietary source
Iron	Not a dietary source
Potassium	Not a dietary source
Copper	Not a dietary source
Phosphorus	Not a dietary source
Magnesium (on anhydrous basis)	20,192 mg / 100 grams
Manganese	Not a dietary source
Sodium	Not a dietary source
Strontium	Not a dietary source
Zinc	Not a dietary source
Calories	Not a dietary source
1. The above values should be considered typical nutritional values. Refer to the Certificate of Analysis for applicable lot specific analytical values. Nutritional values apply solely to USP, EP, BP, JP, FCC, NF, & Purified Grades where applicable.	

PESTICIDE

Magnesium Sulfate Dried USP 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 Dried USP.

PROCESS FLOW CHART



PROPOSITION 65

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