

Safety Data Sheet

acc. To OSHA HCS

Reviewed on 5/23/2022

Printing date 5/23/2022

Trade Name: Isomalt (Ph.Eur./BP/USP-NF/JP)

1 Identification

1.1 Product identifier

Trade name: Isomalt

Product Code: C6001

Application of the substance / the mixture: Pharma Excipient

1.2 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

SpecializedRx Products, LLC

7237 University Ave. NE

Fridley, MN 55432

www.specializedrx.com

sales@specializedrx.com

Information department:

Tel.: 1-888-512-1209

Fax: 1-612-424-8481

1.3 Emergency telephone number:

Emergency Telephone:

US: 1-888-512-1209

International: 1-888-512-1209

2 Hazard(s) identification

Classification of the substance or mixture:

Not classified as hazardous, according to Regulation (EC) No. 1272/2008

Since it doesn't meet the criteria of Article 31 of the Regulation (EC) No. 1907/2006 (REACH), a Safety Data Sheet (SDS) is legally not required.

GHS Signal Word: N/A

GHS Hazard Phrases:

Not applicable.

GHS Precaution Phrases:

Not applicable.

GHS Response Phrases:

Not applicable

GHS Storage and Disposal Phrases: Dust may form explosive mixture in air.

Eye Contact: Not applicable.

Skin Contact: Not applicable

Ingestion: Not applicable

Inhalation: Not applicable.

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3 Composition/information on ingredients

3.1 Chemical Characterization: Mixture

Description: Crystalline, granular powder

Dangerous components: No dangerous components according to Regulation (EC) No 1907/2006

3.2 Chemical Information:

Chemical Name: Mixture of hydrogenated mono- disaccharides, of which $\geq 86\%$ α -D-glucopyranosyl-1,6-D-sorbitol (1,6-GPS) and α -D-glycopyranosyl-1,1-D-mannitol (1,1-GPM)

Botanical Name: Not applicable

Synonym: Isomalt, hydrogenated isomaltulose

Chemical Formula: C₁₂H₂₄O₁₁

CAS Number: (CAS-No.) 64519-82-0

Alternate CAS Number: (EC-No.) 908-700-6

Molecular Weight: 344.31 g/mol

3.3 Composition:

Chemical Name	CAS Number	% By Weight
Isomalt	64519-82-0	$\geq 86\%$

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

4 First-aid measures

4.1 Description of first aid measures

General information: No special measures required; the product is not toxic.

After inhalation: Supply fresh air; consult doctor in case of complaints. If not breathing, give artificial respiration.

After skin contact: Gently wash with soap and water; remove contaminated clothing.

After eye contact: Rinse eye thoroughly, including under the eyelids. If eye irritation persists, contact medical professional.

After swallowing: If symptoms arise or persist, contact medical professional.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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5 Fire-fighting measures

Fire Fighting Instructions:

AS IN ANY FIRE, WEAR A SELF-CONTAINED BREATHING APPARATUS IN PRESSURE-DEMAND, MSHA/NIOSH (APPROVED OR EQUIVALENT), AND FULL PROTECTIVE GEAR.

Flammable Properties and Hazards:

Material is combustible and will produce hazardous combustion gases or vapors in the event of fire. Avoid dust generation – fine dust dispersed through the air at sufficient concentrations in the presence of an ignition source is a potential dust explosion hazard.

Suitable Extinguishing Media:

Use water spray, dry chemical, carbon dioxide, or sand.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Non-emergency personnel: Avoid breathing dust.

Emergency procedures: Immediately contact emergency personnel; evacuate the area. Avoid breathing dust.

Emergency responders:

Minimize dust generation. Wear suitable protective garments and recommended personal protective equipment.

Evacuate area and limit access; take precautionary measures against static discharge.

Material spilled on hard surfaces/walkways may constitute a serious slip/fall hazard. Spill should be handled by trained personnel equipped with respiratory and eye protection. All personnel should avoid breathing dust.

6.2 Environmental precautions:

No special environmental precautions required.

6.3 Methods and material for containment and cleaning up:

Contain spillage and use non-dust generating methods to clean up spill. Take up mechanically (sweeping/shoveling) and collect in suitable containers for disposal.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

PAC-1: None of the ingredients is listed.

PAC-2: None of the ingredients is listed.

PAC-3: None of the ingredients is listed.

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7 Handling and storage

7.1 Precautions for safe handling:

Avoid generation of airborne dust – dust may form flammable or explosive mixture in air. Take precautions to avoid dust explosion; avoid dust accumulation by maintaining clean workspace. Do not eat/drink/smoke while working with this product. Wash hands and exposed skin before eating/drinking/smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: No special requirements.
Information about storage in one common storage facility: Not required.
Further information about storage conditions: Store in dry area, at room temperature.

7.3 Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

Control Parameters: Contains no substances with occupational exposure limit values.

Eye Protection: Wear safety glasses in events where dust exposure is likely.

Protective Gloves: Wear protective gloves to prevent skin exposure.

Other Protective Clothing: Wear appropriate protective clothing to prevent skin exposure.

Engineering Controls (Ventilation etc.):

Provide adequate ventilation to minimize dust concentrations: either local exhaust or general room ventilation is usually required.

Work/Hygienic/Maintenance Practices:

Handle in accordance with good industrial hygiene and safety practice. Prevent further leakage (in the event of an accident or spillage) if safe to do so. Do not let product enter drains.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance: granular, crystalline, powder

Form: Solid

Color: Off-white

Odor: nearly odorless; (slight product specific odor; sweetish)

pH-value: ca 3.5 – 6.0 at 100g/L

Melting point/Melting range: ca. 140 – 165 °C

Boiling point/Boiling range: No data available

Flash point: No data available

Flammability (solid, gaseous): 15 g/m³ particles <74µ

Ignition temperature: > 420°C

Decomposition temperature: Not determined

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Auto igniting: Not determined

Danger of explosion: see below

Explosion limits:

Lower: 60 g/m³ (medium: (grainsize: 90% < 50µm)

Upper: Not determined.

Vapor pressure: Not determined.

Specific gravity: Not determined

Density: Not determined

Relative density: Not determined.

Vapor density: Not determined.

Evaporation rate: Not determined.

Solubility in / Miscibility with Water: ca. 270 – 485 g/L @ 20°C

Partition coefficient (n-octanol/water): log Pow: -4,2 - -3,7

Viscosity: Not determined.

Dynamic: Not determined.

Kinematic: Not determined.

9.2 Other information:

Dust explosion class: St1

Minimum ignition energy: median – MIE

190µm – 100 - 300mJ

270µm – 300 - 1000mJ

10 Stability and reactivity

10.1 Reactivity: Stable under normal use conditions.

10.2 Chemical stability: Stable under normal use conditions.

10.3 Possibility of hazardous reactions: May form explosive dust-air mixtures when finely dispersed.

10.4 Conditions to avoid: Keep away from sparks/heat/open flame/hot surfaces – no smoking.

10.5 Incompatible materials: Not determined

10.6 Hazardous decomposition products: No decomposition if stored and used as directed.

11 Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity:

LD/LC50 values that are relevant for classification:

- Expert judgement has determined the substance or mixture has no acute oral toxicity

Primary irritant effect:

on the skin: Not classified

on the eye: Dust is a mechanical irritant.

Sensitization: Not classified

Additional toxicological information:

No further relevant information available.

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12 Ecological information

12.1 Toxicity

Product:

Toxicity to fish:	LC50 (Pimephales promelas (fathead minnow)): 13.765 mg/l / 96 h Expert judgement <i>The value is given in analogy to the following substances: 1-O-alpha D-glucopyranosyl-D-mannitol, 6-O-alpha-D-glucopyranosyl-D-glucitol</i>
Toxicity to daphnia and other aquatic invertebrates:	EC50 (Daphnia magna (Water flea)): > 100 mg/l / 48 h Method: OECD Test Guideline 202 Expert judgement <i>The value is given in analogy to the following substances: 6-O-alpha D-glucopyranosyl-D-fructose</i>
Toxicity to algae:	EC50 (green algae): 34.200 g/l / 96 h Expert judgement <i>The value is given in analogy to the following substances: 1-O-alpha D-glucopyranosyl-D-mannitol, 6-O-alpha-D-glucopyranosyl-D-glucitol</i>

12.2 Persistence and degradability

Biodegradability:	Anaerobic degradability: > 90 % (COD) Exposure time: 28 d <i>The value is given in analogy to the following substances: 6-O-alpha D-glucopyranosyl-D-fructose</i>
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12.3 Bioaccumulative potential

Bioaccumulation:	Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.
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12.4 Mobility in soil

Product:

Mobility:	No data available
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12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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12.6 Other adverse effects

Additional ecological information No quantitative data concerning the ecological effects of this product. Ecological injuries are not known or expected under normal use.

13 Disposal considerations

13.1 Waste treatment methods

THIS MATERIAL, AS SUPPLIED, IS NOT A HAZARDOUS WASTE ACCORDING TO FEDERAL REGULATIONS (40 CFR 261). THIS MATERIAL COULD BECOME A HAZARDOUS WASTE IF IT IS MIXED WITH OR OTHERWISE COMES IN CONTACT WITH A HAZARDOUS WASTE, IF CHEMICAL ADDITIONS ARE MADE TO THIS MATERIAL, OR IF THE MATERIAL IS PROCESSED OR OTHERWISE ALTERED. CONSULT 40 CFR 261 TO DETERMINE WHETHER THE ALTERED MATERIAL IS A HAZARDOUS WASTE. CONSULT THE APPROPRIATE STATE, REGIONAL, OR LOCAL REGULATIONS FOR ADDITIONAL REQUIREMENTS.

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14 Transport information

14.1 UN-Number DOT, ADR, ADN, IMDG, IATA	Not Regulated
14.2 UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Not Regulated
14.3 Transport hazard class(es) DOT, ADR, ADN, IMDG, IATA Class	Not Regulated
14.4 Packing group DOT, ADR, IMDG, IATA	Not applicable.
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
UN "Model Regulation":	Not applicable.

15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Major Accident Hazard Legislation:	<i>Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.</i> Not applicable
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15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance.

16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

Department issuing SDS:

SpecializedRx Products, LLC

Quality Assurance

Contact: sales@specializedrx.com

Date of preparation / last revision: 5/23/2022

Abbreviations and acronyms:

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ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LD50: Median lethal dose
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit