

**galenIQ™ (Isomalt Ph.Eur./BP/USP-NF/JP)**

Version: 3.0

Revision Date: 06.06.2018

Print Date: 26.06.2018

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

**1.1 Product identifier**

Trade name : **galenIQ™ (Isomalt Ph.Eur./BP/USP-NF/JP)**  
galenIQ™ is available in different qualities

REACH Registration Number : 01-2120770058-52-0000 Beneo Palatinit GmbH, DE-Mannheim

REACH Substance name : reaction mass of 1-O- $\alpha$ -D-glucopyranosyl-D-mannitol and 6-O- $\alpha$ -D-glucopyranosyl-D-glucitol

CAS-No. : 64519-82-0

EC-No. : 908-700-6

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Use of the Sub-  
stance/Mixture : Pharmaceutical Excipient

**1.3 Details of the supplier of the safety data sheet**

Company : BENE0-Palatinit GmbH  
Maximilianstraße 10  
68165 Mannheim, DE

E-mail address : info-MSDS@beneo-group.com

Telephone : +49621421150

Telefax : +49621421160

E-mail address of person  
responsible for the SDS : CRDS EH&S Ochsenfurt (info-msds@suedzucker.de)

**1.4 Emergency telephone number**

: +49621421150 (Mo-Fr: 8 a.m. - 3 p.m.)

**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

**Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

**2.2 Label elements**

**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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

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**2.3 Other hazards**

Dust may form explosive mixture in air.

**SECTION 3: Composition/information on ingredients**

**3.1 Substances**

Synonyms : Isomalt, hydrogenated Isomaltulose

Chemical nature : Mixture of hydrogenated mono- and disaccharides, of this  $\geq$  86 % alpha-D-glucopyranosyl-1,6-D-sorbitol (1,6-GPS) and alpha-D-glucopyranosyl-1,1-D-mannitol (1,1-GPM)

**Hazardous components**

Remarks : No dangerous ingredients according to Regulation (EC) No. 1907/2006

**SECTION 4: First aid measures**

**4.1 Description of first aid measures**

General advice : The product is not toxic.

If inhaled : Fresh air. If symptoms persist, call a physician.

In case of skin contact : Wash off with plenty of water.

In case of eye contact : Rinse thoroughly with plenty of water, also under the eyelids. If eye irritation persists, consult a specialist.

If swallowed : If symptoms persist, call a physician.

**4.2 Most important symptoms and effects, both acute and delayed**

Symptoms : No information available.

**4.3 Indication of any immediate medical attention and special treatment needed**

Treatment : Treat symptomatically.

**SECTION 5: Firefighting measures**

**5.1 Extinguishing media**

Suitable extinguishing media : water spray  
Sand

**5.2 Special hazards arising from the substance or mixture**

Specific hazards during fire- : Combustible material. Development of hazardous combustion

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fighting gases or vapours possible in the event of fire.

**5.3 Advice for firefighters**

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

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**SECTION 6: Accidental release measures**

**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Avoid breathing dust.

**6.2 Environmental precautions**

Environmental precautions : No special environmental precautions required.

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Take up dry (mechanical). Forward for disposal. Clean up affected area. Avoid dust formation.

**6.4 Reference to other sections**

Refer to protective measures listed in sections 7 and 8.

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**SECTION 7: Handling and storage**

**7.1 Precautions for safe handling**

Advice on safe handling : Avoid dust formation. Do not breathe dust.

Advice on protection against fire and explosion : Take precautions against dust explosion. Keep workplaces clean, avoid dust accumulation. Keep away from sources of ignition - No smoking. Observe explosion protection regulations!

Hygiene measures : Wash hands before breaks and at the end of workday.

Dust explosion class : St1

**7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers : Keep in a dry place. Store at room temperature.

**7.3 Specific end use(s)**

Specific use(s) : This information is not available.

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Personal protective equipment

- Eye protection* : Safety glasses  
(in case of dust exposure)
- Hand protection* : For prolonged or repeated contact use protective gloves.
- Respiratory protection* : Respirator must be worn if exposed to dust.  
Suitable mask with particle filter P1 (EN 143)
- Protective measures : Do not breathe dust.  
When using do not smoke.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : crystalline, powder, granular
- Colour : off-white
- Odour : nearly odourless (slight product specific odour, sweetish)
- pH : ca. 3,5 - 6,0  
Concentration: 100 g/l
- Melting point/range : ca. 140 - 165 °C
- Boiling point/boiling range : No data available
- Flash point : No data available
- Upper explosion limit : No data available
- Lower explosion limit : Dust may form explosive mixture in air.  
  
60 g/m<sup>3</sup>  
Medium: (grainsize: 90 % < 50 µm)
- Bulk density : No data available
- Water solubility : ca. 270 - 485 g/l (20 °C)
- Partition coefficient: n-octanol/water : log Pow: -4,2 - -3,7
- Ignition temperature : >= 420 °C

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Viscosity, kinematic : Not applicable

**9.2 Other information**

Dust explosion class : St1

Minimum ignition energy : median - MIE  
190 µm - 100 - 300 mJ  
370 µm - 300 - 1000 mJ

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**SECTION 10: Stability and reactivity**

**10.1 Reactivity**

No decomposition if stored and applied as directed.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions : Like most organic material in powder form, the product can form explosive dust-air mixtures when finely dispersed in air.

**10.4 Conditions to avoid**

Conditions to avoid : Avoid dust formation.  
Strong heating (decomposition).  
Keep away from heat/sparks/open flames/hot surfaces. No smoking.  
Protect from moisture.

**10.5 Incompatible materials**

Materials to avoid : No data available,

**10.6 Hazardous decomposition products**

No decomposition if stored and applied as directed.

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**SECTION 11: Toxicological information**

**11.1 Information on toxicological effects**

**Acute toxicity**

**Product:**

Acute oral toxicity : LD50: Assessment: The substance or mixture has no acute oral toxicity  
Expert judgement

**Skin corrosion/irritation**

**Product:**

Result: No skin irritation

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**Serious eye damage/eye irritation**

**Product:**

Result: No eye irritation  
Mechanical irritation of the eyes is possible.

**Respiratory or skin sensitisation**

**Product:**

Result: No sensitizing effects known.

**Germ cell mutagenicity**

**Product:**

Germ cell mutagenicity- Assessment : Contains no ingredient listed as a mutagen

**Carcinogenicity**

**Product:**

Carcinogenicity : Contains no ingredient listed as a carcinogen

**Reproductive toxicity**

**Product:**

Reproductive toxicity : Contains no ingredient listed as toxic to reproduction

**STOT - single exposure**

**Product:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

**STOT - repeated exposure**

**Product:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Aspiration toxicity**

No aspiration toxicity classification

**Further information**

galenIQ™ complies with the requirements of the current isomalt monograph in Ph Eur, BP, USP-NF and JP. It is used in oral pharmaceutical formulations.

It is generally regarded as a non toxic, non allergenic, and non irritant material.

Toxicological and metabolic studies on isomalt have been summarized in a WHO report prepared by the FAO/WHO Expert Committee (JECFA), resulting in an acceptable daily intake of 'not specified'.

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## SECTION 12: Ecological information

### 12.1 Toxicity

**Product:**

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

### 12.2 Persistence and degradability

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

### 12.3 Bioaccumulative potential

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

### 12.4 Mobility in soil

**Product:**

- Mobility : No data available

### 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..

### 12.6 Other adverse effects

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

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

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Product : Dispose of in accordance with local regulations.  
Product in solid state can be disposed e.g. as commercial waste.

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## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

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## SECTION 15: Regulatory information

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

Major Accident Hazard Legis- : *Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.*  
lation  
Not applicable

### 15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance.

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## SECTION 16: Other information

### Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea



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Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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