

## galenIQ™ (Isomalt Ph.Eur./BP/USP-NF/JPE)

Version 1.0  
Revision Date 25.11.2014

Print Date 09.01.2015

### 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

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

CAS-No. : 64519-82-0

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

Use of the Substance/Mixture : Pharmaceutical Excipient

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

Company : BENEEO-Palatinit GmbH  
GB Palatinit  
Maximilianstraße 10  
DE - 68165 Mannheim

Telephone : +49621421150  
Telefax : +49621421160  
E-mail address : info-MSDS@beneo-group.com  
Responsible/issuing person : CRDS EH&S Ochsenfurt (info-msds@suedzucker.de)

#### 1.4

**Emergency telephone number** : +49621421150 (Mo-Fr: 8 a.m. - 3 p.m.)

### 2. Hazards identification

#### 2.1 Classification of the substance or mixture

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

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

**Classification (67/548/EEC or 1999/45/EC)**

Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

#### 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.

#### 2.3 Other hazards

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Dust may form explosive mixture in air.

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

### 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.
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#### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment	: Treat symptomatically.
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### 5. Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media	: water spray, Sand,
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#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting	: Combustible material. Risk of dust explosion. Development of hazardous combustion gases or vapours possible in the event of
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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.

**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 materials 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.

**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!

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)**

: This information is not available.

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## 8. Exposure controls/personal protection

### 8.1 Control parameters

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Personal protective equipment

Respiratory protection : Respirator must be worn if exposed to dust.

Suitable mask with particle filter P1 (EN 143)

Hand protection : For prolonged or repeated contact use protective gloves.

Eye protection : Safety glasses  
(in case of dust exposure)

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

Protective measures : Do not breathe dust. When using do not smoke.

#### Environmental exposure controls

General advice : No special environmental precautions required.

## 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Form : crystalline, powder, granular

Colour : off-white

Odour : nearly odourless (slight product specific odour, sweetish)

Flash point : no data available

Ignition temperature :  $\geq 420$  °C

Lower explosion limit : .  
Dust may form explosive mixture in air.

60 g/m<sup>3</sup>  
(grainsize: 90 % < 50 µm)

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Upper explosion limit	:	no data available
Minimum ignition energy (MIE)	:	median - MIE 190 µm - 100 - 300 mJ 370 µm - 300 - 1000 mJ
Auto-ignition temperature	:	not applicable
pH (100,0 g/l)	:	ca. 3,5 - 6,0 (at 20 °C)
Melting point/range	:	ca. 140 - 165 °C
Boiling point/boiling range	:	no data available
Bulk density	:	ca. 320 - 920 kg/m <sup>3</sup> depending on particle size
Water solubility	:	ca. 270 - 485 g/l (at 20 °C)

*9.2 Other information*

**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 : Strong heating (decomposition).  
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

*10.5 Incompatible materials*

Materials to avoid : no data available,

*10.6 Hazardous decomposition products*

Thermal decomposition : No decomposition if stored and applied as directed.

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## 11. Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

Acute oral toxicity : LD50 Oral : no data available

#### Skin corrosion/irritation

Skin irritation : No skin irritation

#### Serious eye damage/eye irritation

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

#### Respiratory or skin sensitisation

Sensitisation : No sensitizing effects known.

#### Target Organ Systemic Toxicant - Single exposure

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

#### Target Organ Systemic Toxicant - Repeated exposure

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

Further information : galenIQ™ complies with the requirements of the current isomalt monograph in Ph Eur, BP, USP-NF and JPE. 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'.

## 12. Ecological information

### 12.1 Toxicity

Toxicity to fish : LC50:  
no data available

### 12.2 Persistence and degradability

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Biodegradability : Anaerobic degradability: > 90 % (COD)

*12.3 Bioaccumulative potential*

Bioaccumulation : no data available

*12.4 Mobility in soil*

Mobility : no data available

*12.5 Results of PBT and vPvB assessment*

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).  
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

*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.

**13. Disposal considerations**

*13.1 Waste treatment methods*

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

**14. Transport information**

Not classified as dangerous in the meaning of transport regulations.

*The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.*

**15. Regulatory information**

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

Major Accident Hazard Legislation : Not covered by the German StörfallV.

*15.2 Chemical Safety Assessment*

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A Chemical Safety Assessment is not required for this substance.

**16. Other information**

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*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.*