

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## SIRUPUS SIMPLEX

EN

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### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name: Preserved sugar syrup  
Sirupus simplex  
Geconserveerde suikersiroop  
Sirop de sucre conservé  
Konservierter Zuckersirup

N° CAS: N/A

N° EC: N/A

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

Identified uses: Active Pharmaceutical Ingredient or Excipient.

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

Company: FRAVER NV  
Keizershoek 336  
2550 Kontich  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

The product is not classified according to the CLP regulation.

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.

Signal word(s): Not applicable.

Hazard statements: Not applicable.

Precautionary statements: Not applicable.

Additional applicable label elements: Not applicable.

#### 2.3 Other hazards

Results of PBT and vPvB assessment: PBT: Not applicable. vPvB: Not applicable.

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Not applicable.

#### 3.2 Mixtures

Mixture of the substances listed below with non-hazardous additions.

##### Dangerous components:

Product name: Sucrose

IUPAC name: (2R,3R,4S,5S,6R)-2-[(2S,3S,4S,5R)-3,4-dihydroxy-2,5-bis(hydroxymethyl)oxolan-2-yl]oxy-6-(hydroxymethyl)oxane-3,4,5-triol

Synonyms: Saccharose  
Sugar  
White sugar

N° CAS: 57-50-1

N° EC: 200-334-9

Molecular Formula: C<sub>12</sub>H<sub>22</sub>O<sub>11</sub>

Content: 50 – 100%

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes: No special measures required.  
After inhalation: Supply fresh air; consult doctor in case of complaints.  
After skin contact: Generally, the product does not irritate the skin.  
After eye contact: Rinse opened eye for several minutes under running water.  
After ingestion: Rinse out mouth and then drink plenty of water.

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

Not available.

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

Not available.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media: CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing media: Not available.

#### 5.2 Special hazards arising from the substance/mixture

Not available.

#### 5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: No special measures required.

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Hazardous combustion products: Not available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

##### For non-emergency personnel

Not required.

##### For emergency responders

Not required.

#### 6.2 Environmental precautions

Dilute with plenty of water.

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

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

#### 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.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling: Prevent formation of dust.

Personal protection: Not available.

Technical protective measures: Prevent formation of dust.

Handling: Not available.

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

Storage: Not available.

Conditions for safe storage, including any incompatibilities: No special requirements.  
Store in cool, dry conditions in well sealed receptacles.

Storage – away from: Store protected from light.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Components with limit values that require monitoring at the workplace: 57-50-1 Sucrose

PEL Long-term value: 15 mg/m<sup>3</sup> (total dust)  
5 mg/m<sup>3</sup> (respirable fraction)

REL Long-term value: 10 mg/m<sup>3</sup> (total dust)  
5 mg/m<sup>3</sup> (respirable fraction)

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TLV Long-term value: 10 mg/m<sup>3</sup>

Additional information: The lists that were valid during the creation were used as basis.

### 8.2 Exposure controls

#### Appropriate engineering control

Not available.

#### Individual protection measures

Eye/face protection: Goggles recommended during refilling.

Skin protection: General protective and hygienic measures: The usual precautionary measures for handling chemicals should be followed.

Hand protection: The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests, no recommendation to the glove material can be given for the product/the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves: The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection: Fresh air mask.

Thermal hazards: Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: Clear, colourless to almost colourless liquid with at most a very weak, peculiar smell and very sweet taste.

Odour: Odourless.

Odour threshold: Not determined.

pH: Not determined.

Melting/freezing point: Undetermined.

Initial boiling point: 100 °C (212 °F)

Boiling range: Not available.

Flash point: Not applicable.

Evaporation rate: Not determined.

Flammability (solid/gas): Not applicable.

Upper/lower flammability or explosive limits: Not determined.

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Vapour pressure:	Not determined.
Vapour density:	Not determined.
Relative density:	1.29 to 1.32
Solubility:	Miscible with ethanol 70% (V/V).
Solubility in water:	Fully miscible.
Partition coefficient (n-octanol/water):	Not determined.
Auto-ignition temperature:	Product is not self igniting.
Decomposition temperature:	Not determined.
Viscosity:	Not determined.
Explosive properties:	Danger of explosion: Product does not present an explosion hazard.
Oxidising properties:	Not available.

### 9.2 Other information

#### Solvent content:

Organic solvents: 0.0 %

Water: 36.0 %

VOC content: 0.0 %

Solids content: 64.0 %

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

### 10.3 Possibility of hazardous reactions

No dangerous reactions known.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Not available.

### 10.6 Hazardous decomposition products

No dangerous decomposition products known.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity: Not available.

Skin corrosion/irritation: No irritating effect.

Serious eye damage/irritation: No irritating effect.

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Respiratory/skin sensitisation:	No sensitising effects known.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	<b>Carcinogenic categories</b> IARC (International Agency for Research on Cancer): None of the ingredients is listed. NTP (National Toxicology Program): None of the ingredients is listed. OSHA-Ca (Occupational Safety & Health Administration): None of the ingredients is listed.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	The product is not subject to classification according to internally approved calculation methods for preparations: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

No further relevant information available. General notes: Generally not hazardous for water.

### 12.5 Results of PBT and vPvB assessment

PBT: Not applicable. vPvB: Not applicable.

### 12.6 Other adverse effects

Not available.

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### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Recommendation: Smaller quantities can be disposed of with household waste.

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Marine pollutant: No.

##### 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.

##### 14.8 Additional transport information

Not available.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

#### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

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### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

#### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

#### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

#### 16.4 Method of classification in case of mixture

Classification based on the main component.

#### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

#### 16.6 Training advisement

Not available.

#### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

FRAVER NV

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