

Revision Date 21-Dec-2020

Revision Number 5

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

### 1.1. Product identifier

Product Description: **alpha-D-Lactose monohydrate**  
Cat No. : **412970000, 412970020, 412970100, 412975000**  
CAS-No **5989-81-1**  
Molecular Formula **C<sub>12</sub> H<sub>22</sub> O<sub>11</sub> . H<sub>2</sub> O**

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

Recommended Use Laboratory chemicals.  
Uses advised against No Information available

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

Company **UK entity/business name**  
Fisher Scientific UK  
Bishop Meadow Road, Loughborough,  
Leicestershire LE11 5RG, United Kingdom

**EU entity/business name**  
Acros Organics BVBA  
Janssen Pharmaceuticaaan 3a  
2440 Geel, Belgium

E-mail address [begel.sdsdesk@thermofisher.com](mailto:begel.sdsdesk@thermofisher.com)

### 1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11  
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99  
**CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### CLP Classification - Regulation (EC) No 1272/2008

#### **Physical hazards**

Based on available data, the classification criteria are not met

#### **Health hazards**

Based on available data, the classification criteria are not met

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## Environmental hazards

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

## 2.2. Label elements

Hazard Statements

Precautionary Statements

## 2.3. Other hazards

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008
.alpha.-D-Glucopyranose, 4-O-.beta.-D-galactopyranosyl-, monohydrate	5989-81-1		>95	-

Full text of Hazard Statements: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get medical attention.
<b>Ingestion</b>	Clean mouth with water. Get medical attention.
<b>Inhalation</b>	Remove from exposure, lie down. Remove to fresh air.
<b>Self-Protection of the First Aider</b>	No special precautions required.

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

No information available.

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

### Notes to Physician

Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1. Extinguishing media

#### Suitable Extinguishing Media

Water spray. Carbon dioxide (CO<sub>2</sub>). Dry chemical. Chemical foam.

#### Extinguishing media which must not be used for safety reasons

No information available.

### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

#### Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>).

### 5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

Ensure adequate ventilation.

### 6.2. Environmental precautions

See Section 12 for additional Ecological Information.

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

Sweep up and shovel into suitable containers for disposal.

### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Avoid contact with skin and eyes. Do not breathe dust.

#### Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

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

Keep in a dry, cool and well-ventilated place. Keep container tightly closed.

Technical Rules for Hazardous Substances (TRGS) 510 Storage Class (LGK)  
(Germany)

Class 11

## 7.3. Specific end use(s)

Use in laboratories

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure limits

List source(s):

#### Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

#### Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

Derived No Effect Level (DNEL) No information available

Route of exposure	Acute effects (local)	Acute effects (systemic)	Chronic effects (local)	Chronic effects (systemic)
Oral Dermal Inhalation				

Predicted No Effect Concentration (PNEC) No information available.

### 8.2. Exposure controls

#### Engineering Measures

None under normal use conditions.

#### Personal protective equipment

**Eye Protection** Wear safety glasses with side shields (or goggles) (European standard - EN 166)

**Hand Protection** Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
Neoprene	recommendations			
Natural rubber				
PVC				

**Skin and body protection** Wear appropriate protective gloves and clothing to prevent skin exposure

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Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves.  
(Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

## Respiratory Protection

No protective equipment is needed under normal use conditions.

## Large scale/emergency use

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced

**Recommended Filter type:** Particle filter 2

## Small scale/Laboratory use

Maintain adequate ventilation

## Environmental exposure controls

No information available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Physical State	Solid	
Appearance	Off-white	
Odor	No information available	
Odor Threshold	No data available	
Melting Point/Range	219 °C / 426.2 °F	
Softening Point	No data available	
Boiling Point/Range	No information available	
Flammability (liquid)	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	
Flash Point	No information available	Method - No information available
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
pH	No information available	
Viscosity	Not applicable	Solid
Water Solubility	Soluble	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	No data available	
Vapor Density	Not applicable	Solid
Particle characteristics	No data available	

### 9.2. Other information

Molecular Formula	C12 H22 O11 . H2 O
Molecular Weight	360.3
Evaporation Rate	Not applicable - Solid

## SECTION 10: STABILITY AND REACTIVITY

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## 10.1. Reactivity

None known, based on information available

## 10.2. Chemical stability

Stable under recommended storage conditions.

## 10.3. Possibility of hazardous reactions

### **Hazardous Polymerization**

Hazardous polymerization does not occur.

### **Hazardous Reactions**

No information available.

## 10.4. Conditions to avoid

Incompatible products.

## 10.5. Incompatible materials

Strong oxidizing agents.

## 10.6. Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### **Product Information**

#### **(a) acute toxicity;**

Oral

No data available

Dermal

No data available

Inhalation

No data available

#### Toxicology data for the components

#### **(b) skin corrosion/irritation;**

No data available

#### **(c) serious eye damage/irritation;**

No data available

#### **(d) respiratory or skin sensitization;**

Respiratory

No data available

Skin

No data available

#### **(e) germ cell mutagenicity;**

No data available

#### **(f) carcinogenicity;**

No data available

There are no known carcinogenic chemicals in this product

#### **(g) reproductive toxicity;**

No data available

#### **(h) STOT-single exposure;**

No data available

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(i) STOT-repeated exposure;	No data available
Target Organs	No information available.
(j) aspiration hazard;	Not applicable Solid
Other Adverse Effects	The toxicological properties have not been fully investigated.
Symptoms / effects, both acute and delayed	No information available.

## 11.2. Information on other hazards

Endocrine Disrupting Properties	Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.
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## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Ecotoxicity effects	Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.
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### 12.2. Persistence and degradability

Persistence	Soluble in water, Persistence is unlikely, based on information available.
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<u>12.3. Bioaccumulative potential</u>	Bioaccumulation is unlikely
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<u>12.4. Mobility in soil</u>	The product is water soluble, and may spread in water systems Will likely be mobile in the environment due to its water solubility. Highly mobile in soils
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<u>12.5. Results of PBT and vPvB assessment</u>	No data available for assessment.
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### 12.6. Endocrine disrupting properties

Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors
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### 12.7. Other adverse effects

Persistent Organic Pollutant	This product does not contain any known or suspected substance
Ozone Depletion Potential	This product does not contain any known or suspected substance

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Waste from Residues/Unused Products	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.
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<b>Contaminated Packaging</b>	Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use empty containers.
<b>European Waste Catalogue (EWC)</b>	According to the European Waste Catalog, Waste Codes are not product specific, but application specific.
<b>Other Information</b>	Waste codes should be assigned by the user based on the application for which the product was used.

## SECTION 14: TRANSPORT INFORMATION

**IMDG/IMO** Not regulated

14.1. UN number  
14.2. UN proper shipping name  
14.3. Transport hazard class(es)  
14.4. Packing group

**ADR** Not regulated

14.1. UN number  
14.2. UN proper shipping name  
14.3. Transport hazard class(es)  
14.4. Packing group

**IATA** Not regulated

14.1. UN number  
14.2. UN proper shipping name  
14.3. Transport hazard class(es)  
14.4. Packing group

14.5. Environmental hazards No hazards identified  
14.6. Special precautions for user No special precautions required  
14.7. Maritime transport in bulk according to IMO instruments Not applicable, packaged goods

## SECTION 15: REGULATORY INFORMATION

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

#### International Inventories

X = listed, Europe (EINECS/ELINCS/NLP), U.S.A. (TSCA), Canada (DSL/NDSL), Philippines (PICCS), China (IECSC), Japan (ENCS), Australia (AICS), Korea (ECL).

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	IECSC	AICS	KECL
.alpha.-D-Glucopyranose, 4-O-.beta.-D-galactopyranosyl-, monohydrate	-	-		-	-	-	-	-	X	X	-

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals  
Not applicable

#### National Regulations

ACR41297



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## WGK Classification

Water endangering class = 3 (self classification)

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

## 15.2. Chemical safety assessment

Chemical Safety Assessment/Reports (CSA/CSR) are not required for mixtures

## SECTION 16: OTHER INFORMATION

### Full text of H-Statements referred to under sections 2 and 3

#### Legend

**CAS** - Chemical Abstracts Service

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**ENCS** - Japanese Existing and New Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**WEL** - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment

**LC50** - Lethal Concentration 50%

**NOEC** - No Observed Effect Concentration

**PBT** - Persistent, Bioaccumulative, Toxic

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer Predicted No Effect Concentration (PNEC)

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**POW** - Partition coefficient Octanol:Water

**vPvB** - very Persistent, very Bioaccumulative

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

**Key literature references and sources for data**

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadviser - LOLI, Merck index, RTECS

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**ATE** - Acute Toxicity Estimate

**VOC** (volatile organic compound)

**Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:**

**Physical hazards** On basis of test data

**Health Hazards** Calculation method

**Environmental hazards** Calculation method

### Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

**Revision Date** 21-Dec-2020

**Revision Summary** Update to CLP Format.

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006  
COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No  
1907/2006**

**Disclaimer**

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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

**End of Safety Data Sheet**