



# MATERIAL SAFETY DATA SHEET

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According to Regulation (EC) No. 1907/2006, SANS 11014:2010,  
29 CFR 1910.1200(g)

### Lactulose concentrate 66% w/v USP/BP/Ph.Eur

#### SECTION 1: Identification of the substances/mixture

##### Product identifier:

Lactulose concentrate USP/BP/Ph.Eur 66% w/v

CAS No.: 4618-18-2

EC No.: 225-027-7

##### Use of substance:

Pharmaceutical substance; do not use for any non-intended use

#### SECTION 2: Hazards identification

##### Classification:

This substance is not classified as hazardous according to Regulation (EC) No. 1272/2008, SANS 10234: 2008 (GHS),  
29 CFR 1910.1200(d).

##### Labelling:

According to Regulation (EC) No. 1272/2008 (CLP), GHS: none.

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

Sum formula: C<sub>12</sub>-H<sub>22</sub>-O<sub>11</sub>

Molecular weight: 342.34

##### Hazardous components:

CAS No. 4618-18-2

Chemical name: 4-O-β-D-Galactopyranosyl-D-fructofuranose (lactulose)

Quantity: 50 - <55%

EC No. 225-027-7

#### SECTION 4: First aid measures

##### Description of first aid measures:

General: in case of accident or unwellness, seek medical advice immediately.

After inhalation: in case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation consult a physician.

After skin contact: gently wash with plenty of soap and water. In case of skin irritation, seek medical advice.

After eye contact: rinse cautiously with water for several minutes. In case of persistent troubles, consult a Ophthalmologist.

After ingestion: dose: 50 ml. In all cases of doubt or when symptoms persist, seek medical advice.

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

Overdose:

Symptoms: few or no symptoms expected. If any, nausea and diarrhea might occur.

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

Treat symptomatically.

#### SECTION 5: Firefighting measures

##### Extinguishing media:

Suitable media: carbon dioxide (CO<sub>2</sub>); dry extinguishing powder; alcohol resistant foam; atomized water.

Unsuitable media: high power water jet.

Special hazards: in case of fire, carbon monoxide and/or carbon dioxide can be released.

Advice: for firefighters: wear a self-contained breathing apparatus and chemical protective clothing.

Additional info: collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Co-ordinate fire-fighting measures to the fire surroundings.

#### SECTION 6: Accidental release measures

##### Environmental precautions:

Discharge into the environment must be avoided.

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

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

Clean contaminated objects and areas thoroughly observing environmental regulations.

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

See protective measures under point 7 and 8.

#### SECTION 7: Handling and storage

##### Precautions for safe handling:

- Advice on safe handling: wear suitable clothing. See section 8.
- Advice on protection against fire and explosion: usual measures for fire prevention.
- General protection and hygiene measures: refer to chapter 8.

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### Conditions for safe storage, including any incompatibles:

- Requirements for storage rooms and vessels: keep container tightly closed in a cool, well-ventilated place.
- Advice on storage compatibility: do not store together with: explosives; oxidizing solids; oxidizing liquids; radioactive substances; infectious substances; food and feeding stuffs.
- Further information on storage conditions: keep the packing dry and well-sealed to prevent contamination and absorption of humidity. Recommended storage temperature 20° C. Protect against: light; UV-radiation/sunlight; heat; moisture.

### SECTION 8: Exposure controls/personal protection

#### Control parameters

- Additional advice on limit values: does not contain substances above concentration limits fixing an occupational exposure limit.

#### Exposure controls

- Appropriate engineering controls: no special measures are necessary.
- Protective and hygiene measures: always close containers tightly after the removal of product. Wash hands before breaks and after work.
- Eye/face protection: no special measures are necessary.
- Hand protection: in case of prolonged or frequently repeated skin contact: wear suitable gloves. Suitable material:
  - FKM (fluor rubber): glove material thickness: 0,4 mm, breakthrough time $\geq$  8 h.
  - Butyl rubber: glove material thickness: 0,5 mm, breakthrough time $\geq$  8 h.
  - CR (polychloroprene, chloroprene rubber): glove material thickness: 0,5 mm, breakthrough time $\geq$  8 h.
  - NBR (nitrile rubber): glove material thickness: 0,35 mm, breakthrough time $\geq$  8 h.
  - PVC (polyvinyl chloride): glove material thickness: 0,5 mm, breakthrough time $\geq$  8 h.
  - Before using check leak tightness / impermeability. In the case of wanting to use the gloves again, clean them before taking off and air them well.
- Skin protection: no special measures are necessary.
- Respiratory protection: with correct and proper use and under normal conditions, breathing protection is not required.
- Environmental exposure controls: no special precautionary measures are necessary.

### SECTION 9: Physical and chemical properties

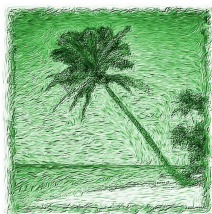
#### Information on basic physical and chemical properties

Physical state: liquid.  
Color: yellow, clear.  
Odor: characteristic.

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pH value:	<u>Test method</u> not determined
<u>Changes in the physical state</u>	
Melting point:	not determined
Initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not determined
Sustaining combustion:	not sustaining combustion
<u>Explosive properties</u>	
None	
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Ignition temperature:	not determined
<u>Auto-ignition temperature</u>	
Gas:	not determined
Decomposition temperature:	not determined
<u>Oxidizing properties</u>	
None	
Vapor pressure:	not determined
Density:	not determined
Water solubility:	not determined
<u>Solubility in other solvents</u>	
Not determined	not determined
Partition coefficient:	not determined
Viscosity / dynamic:	not determined
Viscosity / kinematic:	not determined
Flow time:	not determined
Vapor density:	not determined
Evaporation rate:	not determined
Solvent separation test:	not determined
Solvent content:	not determined
<u>Other information:</u>	
Solid content	not determined

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### SECTION 10: Stability and reactivity

<u>Reactivity:</u>	no information available
<u>Chemical stability:</u>	the product is chemically stable under recommended conditions of storage, use and temperature.
<u>Possibility of hazardous reactions:</u>	no information available.
<u>Conditions to avoid:</u>	protect against: UV-radiation/sunlight; heat.
<u>Incompatible materials:</u>	materials to avoid: oxidizing agents, strong. Reducing agents, strong
<u>Hazardous decomposition products:</u>	can be released in case of fire: Carbon monoxide. Carbon dioxide.

### SECTION 11: Toxicological effects

#### Information on toxicological effects

- Toxicokinetics, metabolism, distribution: no data available.
- Acute toxicity: no data available.

CAS No.	Chemical name	Exposure routes	Method	Dose	Species	Source
4618-18-2	4-O- $\beta$ -D-Galactopyranosyl-D-fructofuranose (lactulose)	Oral	LD50	18100 mg/kg	Rat	RTECS LS696500
- Irritation and corrosivity: no data available.
- Sensitizing effects: no data available.
- STOT-single exposure: no data available.
- Severe effects after repeated or prolonged Exposure: no data available.
- Carcinogenic/mutagenic/toxic effects for reproduction:
  - Carcinogenic (NTP): not listed.
  - Carcinogenicity (IARC): IARC: no component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.
  - Carcinogenicity (OSHA): not listed.
- Aspiration hazard: no data available.
- Specific effects in experiment on an animal: no data available

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### SECTION 12: Ecological information

<u>Toxicity:</u>	no data available.
<u>Persistence and degradability:</u>	no data available.
<u>Bio accumulative potential:</u>	no indication of bioaccumulation potential.
<u>Mobility in soil:</u>	no data available.
<u>Results of PBT and vPvB assessment:</u>	this substance does not meet the PBT/vPvB criteria of REACH, annex XIII.
<u>Other adverse effects:</u>	no data available.
<u>Further information:</u>	do not allow to enter into surface water or drains.

### SECTION 13: Disposal considerations

#### Advice on disposal:

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.  
Non-contaminated packages may be recycled.  
According to EAKV, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.  
Control report for waste code/waste marking according to EAKV:

#### **Waste disposal number of waste from residues/unused products**

070599 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of pharmaceuticals; wastes not otherwise specified.

#### **Waste disposal number of waste from used products**

070599 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of pharmaceuticals; wastes not otherwise specified.

#### **Waste disposal number of contaminated packaging**

150203 WASTE PACKAGING, ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; absorbents, filter materials, wiping cloths and protective clothing; absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02

#### **Contaminated packaging**

Handle contaminated packages in the same way as the substance itself.

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### SECTION 14: Transport information

#### Land transport (ADR/RID/(SANS/ 10228:2012)/US DOT 49 CFR 172.101)

<b>14.1 UN number:</b>	no dangerous good in sense of this transport regulation
<b>14.2 UN proper shipping name:</b>	no dangerous good in sense of this transport regulation
<b>14.3 Transport hazard class(es):</b>	no dangerous good in sense of this transport regulation
<b>14.4 Packing group:</b>	no dangerous good in sense of this transport regulation

#### Inland waterways transport (ADN)

<b>14.1 UN number:</b>	no dangerous good in sense of this transport regulation
<b>14.2 UN proper shipping name:</b>	no dangerous good in sense of this transport regulation
<b>14.3 Transport hazard class(es):</b>	no dangerous good in sense of this transport regulation
<b>14.4 Packing group:</b>	no dangerous good in sense of this transport regulation

#### Marine transport (IMDG)

<b>14.1 UN number:</b>	no dangerous good in sense of this transport regulation
<b>14.2 UN proper shipping name:</b>	no dangerous good in sense of this transport regulation
<b>14.3 Transport hazard class(es):</b>	no dangerous good in sense of this transport regulation
<b>14.4 Packing group:</b>	no dangerous good in sense of this transport regulation

#### Air transport (ICAO)

<b>14.1 UN number:</b>	no dangerous good in sense of this transport regulation
<b>14.2 UN proper shipping name:</b>	no dangerous good in sense of this transport regulation
<b>14.3 Transport hazard class(es):</b>	no dangerous good in sense of this transport regulation
<b>14.4 Packing group:</b>	no dangerous good in sense of this transport regulation
<b>14.5 Environmental hazards:</b>	environmentally hazardous: no
<b>14.6 Special precautions for user:</b>	refer chapter 6-8
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:</b>	not relevant

### SECTION 15: Regulatory information

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

##### **EU regulatory information:**

2010/75/EU (VOC): no information available

##### **Additional information:**

This substance is classified as not hazardous according to regulation (EC) no. 1272/2008 (CLP)

REACH 1907/2006 Appendix XVII: not relevant

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#### National regulatory information:

Water containing class (D): 1 – slightly water contaminating

#### Standards/Regulations:

SANS 10234: 2008  
SANS 11014: 2010  
SANS 10228: 2012  
SANS 10263-0 (2010)  
Gazette No. 36784 of 23 August 2013

#### U.S. Regulations:

##### National Inventory TSCA

4-O-β-D-Galactopyranosyl-D-fructofuranose (lactulose): listed

#### State Regulations:

##### Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, State of California)

This product contains no chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

#### Hazardous Materials Information Label (HMIS):

Health: 0  
Flammability: 0  
Physical Hazard: 1  
Personal Protection:

#### NFPA Hazard Ratings:

Health: 0  
Flammability: 0  
Reactivity: 0  
Unique Hazard:



#### 15.2 Chemical safety assessment

For this substance, a chemical safety assessment has not been carried out.

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### SECTION 16: Other information

Changes:

Rev. 1.0; Initial release: 09-11-2015

Abbreviations and acronyms:

- ADR: Accord européen sur le transport des marchandises Dangereuses par Route
- CAS: Chemical Abstracts Service
- DNEL: Derived No Effect Level
- IARC: International Agency for Research on Cancer
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- IATA-DGR: Dangerous Goods Regulations by "International Air Transport Association"(IATA)
- ICAO: International Civil Aviation Organization
- ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
- GHS: Globally Harmonized System of Classification and Labelling of Chemicals
- GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
- LOAEL: Lowest Observed Adverse Effect Level
- LOAEC: Lowest Observed Adverse Effect Concentration
- LC50: Lethal Concentration, 50 percent
- LD50: Lethal dose, 50 percent
- NOAEC: No Observed Adverse Effect Level
- NOAEL: No Observed Adverse Effect Level
- NTP: National Toxicology Program
- N/A: Not Applicable
- OSHA: Concerning the International Transport of Dangerous Goods by Rail
- PNEC: Predicted No Effect Concentration
- PBT: Persistent Bio accumulative Toxic
- RID: Reglement International concernant le transport des marchandises Dangereuses par Chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- SARA: Superfund Amendments and Reauthorization Act
- SVHC: Substance of Very High Concern
- TRGS: Technische Regeln für Gefahrstoffe
- TSCA: Toxic Substances Control Act
- VOC: Volatile Organic Compounds
- VwVwS: Verwaltungsvorschrift wassergefährdender Stoffe
- WGK: Wassergefährdungsklasse

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#### Further information:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport, and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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