

Safety Data Sheet

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

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

Document no. MSDS 048 | Revision no. 003

QA Sign and Date:  07/07/16

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

1.1. Product identifier

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

CAS No: 4618-18-2

EC No: 225-027-7

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

Use of the substance/mixture

Pharmaceutical substance

Uses advised against

Any non-intended use.

1.3. Details of the supplier of the safety data sheet

Company name: Relax Limited
Level 3, Skyparks Business Centre
Street: Malta International Airport
Place: Luqa LQA 4000 – Malta
Telephone: +356 21 651530
Telefax: +356 21 651161
Responsible Department: admin@relaxlactulose.com

1.4. Emergency telephone number: +356 21 651530

Further Information

Voluntary safety information following the Safety Data Sheet format according to Regulation (EC) No. 1907/2006 (REACH)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008, SANS 10234: 2008 (GHS), 29 CFR Part 1910.1200

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

2.2. Label elements

Additional advice on labelling

Labelling according to Regulation (EC) No. 1272/2008 [CLP], GHS: none

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2.3. Other hazards

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

No risks worthy of mention. Please observe the information on the safety data sheet at all times.

SECTION 3: Composition/information on ingredients

3.1. Substances

Sum formula: C12-H22-O11

Molecular weight: 342.34

Hazardous components

CAS No	Chemical name	Quantity
	EC No	Index No
	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP], SANS 10234: 2008 (GHS), 29 CFR 1910.1200(d). : None	
4618-18-2	4-O-β-D-Galactopyranosyl-D-fructofuranose (Lactulose)	50 - < 55 %
	225-027-7	

Full text of H and EUH statements: see section 16.

Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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 contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes

Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Dose: 50 ml

In all cases of doubt, or when symptoms persist, seek medical advice.

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

Overdose:

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

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

Treat symptomatically.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO₂). Dry extinguishing powder. alcohol resistant foam. Atomized water.

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO₂).

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information

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

6.1. Personal precautions, protective equipment and emergency procedures

See protective measures under point 7 and 8.

6.2. Environmental precautions

Discharge into the environment must be avoided.

6.3. 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.

6.4. Reference to other sections

See protective measures under point 7 and 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear suitable protective clothing. See section 8.

Advice on protection against fire and explosion

Usual measures for fire prevention.

Further information on handling

General protection and hygiene measures: refer to chapter 8

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

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

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Advice on storage compatibility

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and feedingstuffs.

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.

7.3. Specific end use(s)

Refer to chapter 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2. 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 (fluororubber). - Thickness of glove material: 0,4 mm

Breakthrough time \geq 8 h

Butyl rubber. - Thickness of glove material: 0,5 mm

Breakthrough time \geq 8 h

CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm

Breakthrough time \geq 8 h

NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm

Breakthrough time \geq 8 h

PVC (Polyvinyl chloride). - Thickness of glove material: 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.

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Environmental exposure controls

No special precautionary measures are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: liquid

Colour: yellow, clear

Odour: characteristic

pH-Value:

Changes in the physical state

Melting point:

Initial boiling point and boiling range:

Sublimation point:

Softening point:

Pour point:

Flash point:

Sustaining combustion:

Explosive properties

none

Lower explosion limits:

Upper explosion limits:

Ignition temperature:

Auto-ignition temperature

Gas:

Decomposition temperature:

Oxidizing properties

none

Vapour pressure:

Density:

Water solubility:

Solubility in other solvents

not determined

Partition coefficient:

Viscosity / dynamic:

Viscosity / kinematic:

Flow time:

Vapour density:

Evaporation rate:

Solvent separation test:

Solvent content:

Test method

not determined

not determined

not determined

not determined

not determined

not determined

not determined

not sustaining combustion

not determined

not determined

not determined

not determined

not determined

not determined

not determined

not determined

not determined

not determined

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not determined

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not determined

not determined

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9.2. Other information

Solid content: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO₂).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicokinetics, metabolism and distribution

No data available.

Acute toxicity

No data available.

CAS No	Chemical name	Exposure routes	Method	Dose	Species	Source
4618-18-2	4-O-β-D-Galactopyranosyl-D-fructofuranose (Lactulose)	oral	LD50	18100 mg/kg	Rat	RTECS LS6965000

Irritation and corrosivity

No data available

Sensitising effects

No data available.

STOT-single exposure

No data available.

Severe effects after repeated or prolonged exposure

No data available.

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Carcinogenic/mutagenic/toxic effects for reproduction

Carcinogenicity (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.

SECTION 12: Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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.

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Waste disposal number of used product

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.

SECTION 14: Transport information

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

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.
14.5. Environmental hazards:	
ENVIRONMENTALLY HAZARDOUS:	No.
14.6. Special precautions for user	Refer to chapter 6-8.
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	
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.

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2004/42/EC (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

National regulatory information

Water contaminating 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.

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

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IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "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
NOAEL: No observed adverse effect level
NOAEC: 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 bioaccumulative toxic
RID: Règlement 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

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.