Safety data sheet
according to Regulation (EC) No 1907/2006

Lactulose Concentrate 52% w/w, 66% w/v, 70% w/v

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

1.1 Product identifier

Chemical name	4-O-beta-D-galactopyranosyl-beta-D-fructofuranose solution
Synonyms	Lactulose Concentrate USP/BP/Ph.Eur. 52% w/w Lactulose Concentrate USP/BP/Ph.Eur. 66% w/v Lactulose Concentrate USP/BP/Ph.Eur. 70% w/v
CAS-No.	4618-18-2
EC-No.	225-027-7
Registration number	Not applicable for exempted uses.

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

Relevant identified uses of the substance or mixture

Use as a medicinal drug.

Uses of the substance or mixture advised against

Any non-intended use.

1.3 Details of the supplier of the safety data sheet

Supplier	Relax Limited
Address	Level 3, Skyparks Business Centre Malta International Airport Luqa, LQA 4000 Malta
Telephone number	+356 7945 0880
E-mail address	austin@relaxlactulose.com

1.4 Emergency telephone number

Emergency	+356 7945 0880
Medical information	
– **United Kingdom**	844 892 0111 National Poisons Information Service
– **Worldwide**	Internet address: http://apps.who.int/poisoncentres/

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

According to Regulation (EC) No. 1272/2008 (CLP-regulation)

Classification Not classified.

2.2 Label elements

None.

2.3 Other hazards

Lactulose does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006 and is not included in the ECHA endocrine disruptor assessment list.

SECTION 3: Composition / information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Ingredients	**Identity**	**Classification**	**Percentages**
Lactulose		Not classified	52% w/w
CAS-No.	4618-18-2		66% w/v
EC-No.	225-027-7		70% w/v
Registration No.	Exempt		

SECTION 4: First aid measures

4.1 Description of first aid measures

General information In case of accident, or if you feel unwell, seek medical advice.

Inhalation Not applicable.

Skin contact Rinse skin with plenty of water and soap. In case of skin irritation, seek medical treatment.water or shower.

Eye contact First rinse with plenty of water (remove lenses if possible). If eye irritation persists: get medical advice / attention.

Ingestion Rinse mouth. Drink plenty of water and call a doctor / physician if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Acute symptoms and effects from exposure in the event of excessive dosage

Few or no symptoms expected. If any, nausea and diarrhoea might occur.

Delayed symptoms and effects from exposure

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Information on medical attendance

No special measures required. Treat symptomatically.

Special means to provide treatment at the workplace

No special measures required. Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Not applicable. The liquid is not flammable.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

In case of fire: carbon monoxide and carbon dioxide containing combustion gases may be released.

5.3 Advice for fire-fighters

Protective actions

Use water spray to cool exposed containers in the environment.
Retain contaminated extinguishing water; do not allow entering drains, water courses or soil.

Special protective equipment

In case of larger fires: self-contained respiratory protective device, fully protective suit.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Information for non-emergency personnel

Gloves, boots, protective clothing.

Information for emergency responders

For advice on personal protection clothing, see chapter 8.

6.2 Environmental precautions

Try to prevent the material from entering drains, water courses or soil.

Advise authorities if spillage has entered water course or sewer or has contaminated soil.

6.3 Methods and material for containment and cleaning up

In the case of large quantities: dam spilled substance in and remove with a vacuum cleaner; recycle if possible. Wash away remainder with water.
Take up small amounts spilled product with an absorbent. Dispose of in a suitable waste disposal container.

6.4 Reference to other sections

See Section 8 for more detailed advice on personal protective equipment and section 13 on waste disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations for safe handling

The usual precautionary measures when handling chemicals have to be observed.

Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

7.2 Conditions for safe storage, including any incompatibilities

Conditions for safe storage

Store in a well-ventilated place. Keep containers tightly closed.
Keep away from strong oxidizing agents and strong reducing agents, radioactive substances, infectious substances, food and feedingstuffs.

Protection against ambient influences

Keep the packing dry and well-sealed to prevent contamination and absorption of moisture.
Do not refrigerate or freeze. Do not store above 25°C.
Recommended storage temperature: 20 °C.

7.3 Specific end use(s)

See section 1.

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Limit values				
8 hours (TWA)		Short term (15 min)		Remark
mg/m^3	ppm	mg/m^3	ppm	
not established		not established		

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Ventilation.

8.2.2 Individual protection measures, such as personal protective

a) Eye/face protection

Safety goggles (EN 166).

b) Skin protection

Hand protection	Gloves butyl rubber 0.5 mm	Breakthrough time > 8 hours (EN 374)
	Gloves nitrile rubber (NBR) 0.35 mm	Breakthrough time > 8 hours (EN 374)
	Gloves polyethylene (LLDPE) 0.75 mm	Breakthrough time > 8 hours (EN 374)
Other	Protective clothing (EN 340 / EN 14605).	

c) Respiratory protection

Under normal conditions, breathing protection is not required.

d) Thermal hazards Not applicable.

8.2.3 Environmental exposure controls

Direct polluted air of the local exhaust ventilation out of the plant in a manner in accordance with environmental regulations.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

(a)	**Physical state**	Liquid
(b)	**Colour**	Colourless to yellow
(c)	**Odour / Odour threshold (mg/m3**	Characteristic
(d)	**Melting point / freezing point (˚C)**	< 0
(e)	**Boiling point (˚C)**	> 100
(f)	**Flammability**	Not flammable
(g)	**Lower and upper explosion limit (vol%)**	Not applicable
(h)	**Flash point (˚C)**	Not applicable
(i)	**Auto-ignition temperature (˚C)**	Not applicable
(j)	**Decomposition temperature (˚C)**	No data available
(k)	**pH (100 g/L at 20 °C)**	4.8 – 6.0
(l)	**Kinematic viscosity (mm^2/s)**	No data available
(m)	**Solubility in water at 20 ˚C (g/L)**	Miscible with water
(n)	**Partition coefficient n-octanol/water (log value)**	– 4.7
(o)	**Vapour pressure at 20 ˚C (hPa)**	No data available
(p)	**Density (g/cm^3) and/or Relative density (water = 1)**	52% w/w: 1.360 66% w/v: 1.340 70% w/v: 1.360
(q)	**Relative vapour density (air = 1)**	No data available
(r)	**Particle characteristics (particle size)**	Not applicable.

9.2 Other information

9.2.1	**Information with regard to physical hazard classes**	Not classified
9.2.2	**Other safety characteristics**	
	Miscibility	Miscible with water.

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction when the regulations for handling and storage are observed.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Exothermic reactions with strong oxidizers possible.

10.4 Conditions to avoid

UV-radiation/sunlight, heat.

10.5 Incompatible materials

Strong oxidizing agents and strong reducing agents.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11 Toxicological information

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

a) Acute Toxicity

– ***Oral***	LD50 (rat)	18100 mg/kg
– ***Dermal***	LD50 (rabbit)	No data available
– ***Inhalative***	LC50 (rat, 4 hours)	No data available

b) Skin corrosion/irritation

No test data available.

c) Serious eye damage/irritation

No test data available.

d) Respiratory or skin sensitisation

No test data available.

e) Germ cell mutagenicity

No test data available.

f) Carcinogenicity

No carcinogenic effects observed.

g) Reproductive toxicity

No test data available.

h) Specific target organ toxicity – single exposure

No test data available.

i) Specific target organ toxicity – repeated exposure

No test data available.

j) Aspiration hazard

No indication that the substance may cause aspiration toxicity.

11.1.1 Information on likely routes of exposure

– ***Absorption***	Lactulose is poorly absorbed from the gastrointestinal tract and no enzyme capable of hydrolysis of this disaccharide is present in human gastrointestinal tissue.
– ***Distribution***	Oral doses of lactulose reach the colon virtually unchanged.
– ***Metabolism***	In the colon, lactulose is broken down primarily to lactic acid, and also to small amounts of formic and acetic acids, by the action of colonic bacteria, which results in an increase in osmotic pressure and slight acidification of the colonic contents.
– ***Elimination***	Urinary excretion has been determined to be 3% or less and is essentially complete within 24 hours.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

No endocrine disrupting properties identified.

11.2.2 Other information

No data available.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

- ***Fish*** No test data available.
- ***Aquatic invertebrates*** No test data available.
- ***Algae and cyanobacteria*** No test data available.

12.2 Persistence and degradability

Stability

- ***Hydrolysis*** Stable for at least 2 years.
- ***Photolysis*** Not susceptible to photolysis.

Biodegradability

- ***Biodegradation in water*** Readily biodegradable.

12.3 Bioaccumulation potential

Aquatic bioaccumulation BCF (based on regression-based estimate). 3.1
No remarkable bioaccumulation potential (log K_{ow} < 4 and BCF < 500).

12.4 Mobility in soil

Adsorption/desorption K_{oc} at 20 °C (calculated) 2.5
No significant adsorption to soil or sediment.

12.5 Results of PBT and vPvB assessment

The substance does not meet the PBT and vPvB criteria according to annex XIII of Regulation (EC) No 1907/2006.

12.6 Endocrine disrupting properties

Adverse environmental effects of endocrine disruptors are not relevant.

12.7 Other adverse effects

Low hazard to water (Water hazard class 1, WGK Germany)

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product disposal Dispose of as industrial waste in accordance with local legislation.
Prevent the waste from entering the sewage system.

Packaging disposal Dispose of packages with remainders as industrial waste.
Non-contaminated packages may be recycled.
Cleaned packaging can be re-used.

Waste treatment-relevant information

European waste list (EURAL) 07 05 99

SECTION 14: Transport information

The product is not classified as dangerous according to the regulations for the transport of dangerous goods.

SECTION 15: Regulatory information

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

Authorisations (REACH)

Not subject to Title VII of Regulation (EC) No 1907/2006.

Restrictions (REACH), SVHC

No restrictions according to Title VIII of Regulation (EC) No 1907/2006.
SVHC (Substances of Very High Concern) status: negative

Control of major-accident hazards (Seveso III)	
	Not subject to Directive 2012/18/EU.
Other EU regulations	Additional national regulations have to be observed.

15.2 Chemical safety assessment

CSA	For this product a chemical safety assessment has not been carried out.

SECTION 16: Other information

16.1 Changes to the previous version

Previous version	004
Changes	Adaptations to Regulation (EU) 2020/878

16.2 Abbreviations and acronyms

CAS	Chemical Abstracts Service (Division der American Chemical Society)
CLP	Classification, Labelling and Packaging
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
EC50	Effect Concentration, 50 percent
EC-Number	EINECS-, ELINCS- or CLP-Number
GHS / CLP	Globally Harmonised System / Classification, Labelling and Packaging
IC50	Inhibitory Concentration, 50 percent
LC50	Lethal Concentration, 50 percent
LD50	Lethal Dose, 50 percent
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NOEC	No observed adverse effect concentration
NOEL	No observed effect level
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
ppm	Parts per million
TWA	Time Weighted Average
vPvB	very persistent and very bioaccumulative

16.3 Literature references and sources for data

External Safety Data Sheets, IUCLID Dataset.

16.4 Full text of Hazard statements which are not written out in full under Sections 2 to 15

None.

This data sheet has been compiled by KWA. Despite the careful attention paid to the setting up of the text, KWA cannot be held responsible for any error appearing in the text and resulting in whatever damage it may cause.
KWA, Spijksedijk 18c, 4207 GN Gorinchem, Phone +31 183 649 556