SAFETY DATA SHEETS

This SDS packet was issued with item:

078930157

N/A



Lactulose Solution MATERIAL SAFETY DATA SHEET

According to 1907/2006/EG, article 31 Revision date: 04.11.2010

1. Identification of the Substance / Preparation and the Company / Undertaking

Product name Lactulose solution 50% w / w
Manufacturer Fresenius Kabi Austria GmbH

Estermannstraße 17, A-4020 Linz / Austria

Telephone +43-(0)732-7651 Telefax +43-(0)732-782833

E-mail safety.linz@fresenius-kabi.com

Emergency telephone number +43-(0)732-7651-2408

2. Compostition / Information on Ingredients

Chemical name of the substance Lactulose

Chemical nature Lactulose is a Disaccharide composed of Galactose

and Fructose and represented by the formula

C₁₂H₂₂O₁₁

Synonyms 4-O-B-D-Galactopyranosyl-D-fructose

EEC-No. - Index-No - CAS-No 4618-18-2

Hazardous components According to the EEC criteria this product is not

classified as a hazardous preparation

Hazardous impurities No hazardous impurities

3. Hazards Identification

Most important hazards -Specific hazards --

4. First Aid Measures

General advice -

Major effects exposure -

Inhalation -

Skin contact Rinse with water

Eye contact Rinse with water for a prolonged period whilst keeping

the eyes wide open

If irritation still persists, consult an eye specialist

Ingestion Rinse mouth with water

Protection of first-aiders

Notes to physician -

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5. Fire-Fighting Measures

Suitable extinguishing media Not applicable Extinguishing media which must None known

not be used for safety reasons

Specific hazards

Special protective equipment

for fire-fighters Specific methods

6. Accidential Release Measures

Personnel precautions Chapter 8

Environmental precautions This product does not present any particular risk to

the environment

Avoid direct discharge into drains

Methods for cleaning up Sweep up or vacuum up the product to recover it

7. Handling and Storage

Handling Spills may be slippery

Technical measures /

precautions

Safe handling advice

To guarantee the quality of the product it has to be Storage

protected from direct light and humidity

Store at room temperature

Technical measures /

storage conditions

Room temperature, dry

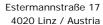
Incompatible products None known

Class

Packing material Normal commercial packing material concerning the

legislation (water resistant material)

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8. Exposure Controls / Personal Protection

Engineering measures to -

reduce exposure

Control parameters -

Personnel protection equipment -

Respiratory protection -

Skin and body protection

Hygiene measures

9. Physical and Chemical Properties

Form Syrup

Colour Slightly yellow

Odour Sweet

pH 3.0 to 7.0

Boiling point / range Melting point / range -

Decomposition temperature > 225°C

Flash point - Autoignition temperature -

Explosion limits - lower -

- upper -

Vapour pressure -

Vapour density - Not a

Bulk densityNot applicableDensity1.3 g / cm³

Solubility Water solubility Very good

Organic solvents No, except DMSO

Fat solubility No

Partition coefficient

(n-octanol / water) -

Viscosity -

Other data See the corresponding product specification

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products

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10. Stability and Reactivity

Stability Stable at room temperature

Conditions to avoid None known Hazardous decomposition None known

Further information -

11. Toxicological Information

Acute toxicity No acute toxicity

Local effects Sensitisation Long term toxicity Specific effects Further information -

12. Ecological Information

Mobility -

Persistence / degradability Biodegradability: > 99%

Bioaccumulation Further information -

13. Disposal Considerations

Waste from residues / Product can be disposed without special precautions unused products Dispose of in accordance with the relevant local

regulations.

Contaminated packaging Does not need cleaning prior to disposal.

Proper waste name Lactulose, solution

Waste code (A)

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14. Transport Information

UN-No -

ADR / RID No subject of ADR / RID regulations

Class – Item – ADR / RID –

Labels

TREM-Card – HI / UN No –

Proper shipping name Lactulose, solution

Class – IMDG Page – Subrisks –

Packaging group – IMO-Labels –

EmS. – MFAG –

Proper shipping name Lactulose, solution

IACO -

UN / ID No. - Class -

Packaging group – IACO-Labels –

Proper shipping name Lactulose, solution

Packaging group –

Further information No transport risks

15. Regulatory Information

According to GefStoffV / EG

Symbol(s) Not required R - phrase(s) Not required S - phrase(s) Not required

According to Ö - Chem / VO

"Wassergefährdungs-Klasse" 0

Further information VbF - / MAK -

16. Other Information

Recommended use Pharmaceutical product

Recommended restrictions Further information -

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