Lactulose Solution
MATERIAL SAFETY DATA SHEET
According to 1907/2006/EG, article 31

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)732/7651-2475

2. Hazards Identification

Most important hazards
-

Specific hazards
-

3. Composition / Information on Ingredients

Chemical name of the substance
Lactulose

Chemical nature
Lactulose ist a Disaccharide compositing of Galactose and Fructose represented by the formula:
\[ C_{12}H_{22}O_{11} \]

Synonyms
4-O-ß-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

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
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Protection of first-aiders -
Notes to physician -

5. Fire-Fighting Measures

Suitable extinguishing media Not flameable
Extinguishing media which must not be used for safety reasons None known
Specific hazards -
Special protective equipment for fire-fighters -
Specific methods -

6. Accidental 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 -
Storage To guarantee the quality of the product it has to be 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).
8. Exposure Controls / Personal Protection

Engineering measures to reduce exposure
- 

Control parameters
- 

Personnel protection equipment
- 

Respiratory protection
- 

Hand protection
- 

Eye protection
- 

Skin and body protection
- 

Hygiene measures
- 

9. Physical and Chemical Properties

Form Syrup

Colour Slightly yellow

Odour Sweet

pH 3,0 - 7,0

Boiling point/range 105°C

Melting point/range -

Decomposition temperature > 225°C

Flash point -

Autoignition temperature -

Explosion limits - lower -

- upper -

Vapour pressure -

Vapour density -
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Bulk density n.a.
Density 1,3 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

10. Stability and Reactivity

Stability Stable at room temperature
Conditions to avoid None known
Hazardous decomposition products 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
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Mobility -
Persistence/degradability Biodegradability: > 99%
Bioaccumulation -
Further Information -

13. Disposal Considerations

Waste from residues/ unused products Product can be disposed without special precautions. 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)

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-Lables -
EmS. MFAG: -
Proper shipping name Lactulose, solution
IACO -
UN/ID No. Class -
Packaging group. IACO-Labels -
Proper shipping name Lactulose, solution
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Revision date: 15.02.2017

Packaging group -

Further Information No transport risks

15. Regulatory Information

According to GHS / CLP regulation:

Symbol(s) not required

H - phrase(s) not required

P - Phrase(s) not required

According to ChemV

„Wassergefährdungs-Klasse“ 0

Further Information VbF - / MAK -

16. Other Information

Recommended Use Pharmaceutical product

Recommended Restrictions

Further Information

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 other materials or any process, unless specified in the text.