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

Revision date: 14.01.2014

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. 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: \( \text{C}_{12}\text{H}_{22}\text{O}_{11} \)
Synonyms | 4-O-ß-D-Galactopyranosyl-D-Fructose
EEC-No. - | Index-No -
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
Lactulose Solution
MATERIAL SAFETY DATA SHEET
According to 1907/2006/EG, article 31

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

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

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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

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**10. Stability and Reactivity**

**Stability**  
Stable at room temperature

**Conditions to avoid**  
None known

**Hazardous decomposition products**  
None known

**Further information**  
-

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**11. Toxicological Information**

**Acute toxicity**  
No acute toxicity

**Local effects**  
-

**Sensitisation**  
-

**Long term toxicity**  
-

**Specific effects**  
-

**Further information**  
-
Lactulose Solution
MATERIAL SAFETY DATA SHEET
According to 1907/2006/EG, article 31

12. Ecological Information

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-Labels -

EmS. - MFAG: -

Proper shipping name Lactulose, solution

IACO -

UN/ID No. - Class -
**Lactulose Solution**

**MATERIAL SAFETY DATA SHEET**

According to 1907/2006/EG, article 31

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**Packaging group.**  
- IACO-Labels -

**Proper shipping name**  
Lactulose, solution

**Packaging group**  
-

**Further Information**  
No transport risks

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**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 -

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**16. Other Information**

**Recommended Use**  
Pharmaceutical product

**Recommended Restrictions**

**Further Information**

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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.