

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

<i>Product name</i>	Lactulose solution 50% w / w
<i>Manufacturer</i>	Fresenius Kabi Austria GmbH Estermannstraße 17, A-4020 Linz / Austria
<i>Telephone</i>	+43-(0)732-7651
<i>Telefax</i>	+43-(0)732-782833
<i>E-mail</i>	safety.linz@fresenius-kabi.com
<i>Emergency telephone number</i>	+43-(0)732-7651-2408

2. Composition / Information on Ingredients

<i>Chemical name of the substance</i>	Lactulose
<i>Chemical nature</i>	Lactulose is a Disaccharide composed of Galactose and Fructose and represented by the formula C₁₂H₂₂O₁₁
<i>Synonyms</i>	4-O-β-D-Galactopyranosyl-D-fructose
<i>EEC-No. -</i>	Index-No - CAS-No 4618-18-2
<i>Hazardous components</i>	According to the EEC criteria this product is not classified as a hazardous preparation
<i>Hazardous impurities</i>	No hazardous impurities

3. Hazards Identification

<i>Most important hazards</i>	-
<i>Specific hazards</i>	-

4. First Aid Measures

<i>General advice</i>	-
<i>Major effects exposure</i>	-
<i>Inhalation</i>	-
<i>Skin contact</i>	Rinse with water
<i>Eye contact</i>	Rinse with water for a prolonged period whilst keeping the eyes wide open If irritation still persists, consult an eye specialist
<i>Ingestion</i>	Rinse mouth with water
<i>Protection of first-aiders</i>	-
<i>Notes to physician</i>	-

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5. Fire-Fighting Measures

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

6. Accidental Release Measures

<i>Personnel precautions</i>	Chapter 8
<i>Environmental precautions</i>	This product does not present any particular risk to the environment Avoid direct discharge into drains
<i>Methods for cleaning up</i>	Sweep up or vacuum up the product to recover it

7. Handling and Storage

<i>Handling</i>	Spills may be slippery
<i>Technical measures / precautions</i>	-
<i>Safe handling advice</i>	-
<i>Storage</i>	To guarantee the quality of the product it has to be protected from direct light and humidity Store at room temperature
<i>Technical measures / storage conditions</i>	Room temperature, dry
<i>Incompatible products</i>	None known
<i>Class</i>	-
<i>Packing material</i>	Normal commercial packing material concerning the legislation (water resistant material)

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8. Exposure Controls / Personal Protection

<i>Engineering measures to reduce exposure</i>	-
<i>Control parameters</i>	-
<i>Personnel protection equipment</i>	-
<i>Respiratory protection</i>	-
<i>Hand protection</i>	-
<i>Eye protection</i>	-
<i>Skin and body protection</i>	-
<i>Hygiene measures</i>	-

9. Physical and Chemical Properties

<i>Form</i>	Syrup	
<i>Colour</i>	Slightly yellow	
<i>Odour</i>	Sweet	
<i>pH</i>	3.0 to 7.0	
<i>Boiling point / range</i>	-	
<i>Melting point / range</i>	-	
<i>Decomposition temperature</i>	> 225°C	
<i>Flash point</i>	-	
<i>Autoignition temperature</i>	-	
<i>Explosion limits</i>	- lower	-
	- upper	-
<i>Vapour pressure</i>	-	
<i>Vapour density</i>	-	
<i>Bulk density</i>	Not applicable	
<i>Density</i>	1.3 g / cm ³	
<i>Solubility</i>	Water solubility	Very good
	Organic solvents	No, except DMSO
	Fat solubility	No
	Partition coefficient (n-octanol / water)	-
<i>Viscosity</i>	-	
<i>Other data</i>	See the corresponding product specification	

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10. Stability and Reactivity

<i>Stability</i>	Stable at room temperature
<i>Conditions to avoid</i>	None known
<i>Hazardous decomposition products</i>	None known
<i>Further information</i>	-

11. Toxicological Information

<i>Acute toxicity</i>	No acute toxicity
<i>Local effects</i>	-
<i>Sensitisation</i>	-
<i>Long term toxicity</i>	-
<i>Specific effects</i>	-
<i>Further information</i>	-

12. Ecological Information

<i>Mobility</i>	-
<i>Persistence / degradability</i>	Biodegradability: > 99%
<i>Bioaccumulation</i>	-
<i>Further information</i>	-

13. Disposal Considerations

<i>Waste from residues / unused products</i>	Product can be disposed without special precautions Dispose of in accordance with the relevant local regulations.
<i>Contaminated packaging</i>	Does not need cleaning prior to disposal.
<i>Proper waste name</i>	Lactulose, solution
<i>Waste code (A)</i>	

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14. Transport Information

<i>UN-No</i>	-	
<i>ADR / RID</i>	No subject of ADR / RID regulations	
<i>Class –</i>	Item –	ADR / RID – Labels
<i>TREM-Card –</i>	HI / UN No –	
<i>Proper shipping name</i>	Lactulose, solution	
<i>Class –</i>	IMDG Page –	Subrisks –
<i>Packaging group –</i>	IMO-Labels –	
<i>EmS. –</i>	MFAG –	
<i>Proper shipping name</i>	Lactulose, solution	
<i>IACO –</i>		
<i>UN / ID No. –</i>	Class –	
<i>Packaging group –</i>	IACO-Labels –	
<i>Proper shipping name</i>	Lactulose, solution	
<i>Packaging group</i>	–	
<i>Further information</i>	No transport risks	

15. Regulatory Information

<i>According to GefStoffV / EG</i>	
<i>Symbol(s)</i>	Not required
<i>R - phrase(s)</i>	Not required
<i>S - phrase(s)</i>	Not required
<i>According to Ö - Chem / VO</i>	
<i>„Wassergefährdungs-Klasse“</i>	0
<i>Further information</i>	VbF - / MAK -

16. Other Information

<i>Recommended use</i>	Pharmaceutical product
<i>Recommended restrictions</i>	-
<i>Further information</i>	-

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