
Effective Date
19-FEB-2004

MATERIAL SAFETY DATA SHEET
LACTULOSE, LIQUID 720g/l

BDIS NL 0510793
MSDS 212
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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Supplier

Solvay Pharmaceuticals B.V.
C.J. van Houtenlaan 36
1381 CP Weesp, The Netherlands
Tel: (31) 294 477 000 Fax: (31) 294 480 253

Identification of the substance or the preparation

Product name

LACTULOSE, LIQUID 720g/l

Chemical name

4-O-β-D-galactopyranosyl-D-fructose

Chemical characterization

Solution of lactulose in water

Recommended uses

- Pharmaceuticals

Molecular formula: $C_{12}H_{22}O_{11}$
Molecular weight: 342.3

2. COMPOSITION/ INFORMATION ON INGREDIENTS

Lactulose

Concentration: > 720 g/l
CAS no: 4618-18-2
EG no: 225-027-7

3. HAZARDS IDENTIFICATION

- Preparation is not dangerous according to Directive 1999/45/EC.
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4. FIRST-AID MEASURES

Inhalation

- Negligible

Eye contact

- Negligible

Skin contact

- Negligible

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Ingestion

If the subject is completely conscious:

- Rinse mouth and administer fresh water.

If the subject is unconscious:

- Not applicable.
-

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

- In case of fire in close proximity, all means of extinguishing are acceptable.

Unsuitable extinguishing media

- No restriction.

Special exposure hazards

- Non-combustible

Protective measures in case of intervention

- The product does not require any special precautions.
-

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

- Follow the protective measures given in section 8.

Environmental precautions

- Prevent discharges into the environment (sewers, rivers, soils,...).

Methods for cleaning up

- Remove the product with an inert absorbent (sand, kieselguhr, vermiculite, ...).
 - Place everything into a closed, labelled container compatible with the product.
 - Clean the area with large quantities of water.
 - For disposal methods, refer to section 13.
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7. HANDLING AND STORAGE

Handling

- Negligible.

Storage

- Keep in original packaging, closed.
- Protect from light.

Specific uses

- For any particular use, please contact the supplier.

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Packaging

- PE
- Glass

Other precautions

- Follow the protective measures given in section 8.
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8. EXPOSURE CONTROL/PERSONAL PROTECTION

Exposure controls

- Follow the protective measures given in section 7.
- Maintain employee exposures to levels below the applicable exposure limit.

Exposure limit values

- Lactulose
SAEL (Solvay): TWA (8 h): 10 mg/m³

Respiratory protection

- Not applicable

Hand protection

- Negligible

Eye protection

- Wear protective goggles for all industrial operations.

Skin protection

- Negligible

Other precautions

- Negligible

Environmental exposure controls

- Respect local/federal and national regulations for aquatic emissions (see section 15).
-

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: viscous liquid
Colour: colourless to yellow

Change of state

- Melting point: > 169°C (lactulose crystalline)
- Boiling point: no data

Flash point

- Non-flammable

Vapour pressure

- No data

Density

- Specific gravity: 1.3 – 1.4

Solubility

- Water: > 685 g/kg (temperature 25°C, lactulose crystalline)

pH

- = 3 – 7 (10% solution, temperature 25°C).

Partition coefficient (octanol/water)

- = -4.7 (calculated value, lactulose crystalline)

Explosivity

- No data
-

10. STABILITY AND REACTIVITY

Conditions to avoid

- Negligible

Materials to avoid

- Negligible

Dangerous decomposition products

- Carbon monoxide
-

11. TOXICOLOGICAL INFORMATION

11.1 Toxicological data

Acute toxicity

- Oral route, LD₅₀, rat 30 - 45 ml/kg

Chronic toxicity

- Oral route (diet), after prolonged exposure, rat, 15 ml/kg, no observed effect.
- Oral route (diet), after prolonged exposure, dog, target organ: gastro-intestinal system, 4 ml/kg, observed effect.
- No effect on fertility.
- No teratogenic effect.

Comments

- No appreciable toxic effect.

11.2 Health effects

Inhalation

- Negligible

Eye contact

- Negligible

Skin contact

- Negligible

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Ingestion

- Abdominal cramps and diarrhoea.
 - By ingestion of large quantities: nausea and vomiting.
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12. ECOLOGICAL INFORMATION (DATA OF LACTULOSE CRYSTALLINE)

Acute toxicity

- Crustaceans, *Daphnia magna*, EC₅₀, 48 h, > 100 mg/l.
- Fishes, *Brachydanio rerio*, LC₅₀, 96 h, > 100 mg/l.
- Algae, *Selenastrum capricornutum*, EC₅₀ (growth), 72 h, > 100 mg/l.

Mobility

- Water/soil; result: considerable solubility and mobility.
- Soil/sediments, log KOC = 0.4; result: non-significant adsorption.

Biodegradation

- Aerobic, test: readily biodegradability/closed bottle, degradation 65%, 28 days, result: readily biodegradable.

Potential for bioaccumulation

- Bioconcentration: log P o/w = -4.7; result: improbable bioaccumulation .

Comments

- Product is not significant hazardous for the aquatic environment.
-

13. DISPOSAL CONSIDERATIONS

Waste treatment

- Dispose in compliance with local/federal and national regulations.
- Send the product to an authorised industrial waste incinerator.
- Or, the product can be discharged into a biological treatment plant.

Packaging treatment

- Containers that cannot be cleaned must be treated as waste.
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14. TRANSPORT INFORMATION

- Not classified as dangerous
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15. REGULATORY INFORMATION

EC labelling

Not dangerous according to Directive 1999/45/EC.

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16. OTHER INFORMATION

Reason for update

General revision according to Directive 2001/58/EC

Addition of algae toxicity data (section 12) and log P (o/w) (section 9).

Change of product name

The information given corresponds to the current state of our knowledge and experience of the product, and is not exhaustive. This applies to product which conforms to the specification, unless otherwise stated. In the cases of combinations and mixtures one must make sure that no new dangers can arise. In any case, the user is not exempt from observing all legal, administrative and regulatory procedures relating to the product, personal hygiene, and protection of human welfare and the environment.