

**MATERIAL SAFETY DATA SHEET****LACTULOSE CONCENTRATE USP / LIQUID Ph. EUR****1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING****1.1 Identification of the substance and preparation**

Product name : LACTULOSE, LIQUID (Ph Eur.) or  
LACTULOSE CONCENTRATE (USP)  
Chemical name : 4-O-beta-D-galactopyranosyl-D-fructose  
Chemical characterisation : Solution of lactulose in water  
Formula :  $C_{12}H_{22}O_{11}$   
Molecular weight : 342.3

**1.2 Use of the substance/preparation**

Recommended uses : Pharmaceuticals

**1.3 Company/undertaking identification**

Canlac, Division of Solvay Pharma Inc.  
75, boul. Industriel est, C.P. 307  
Victoriaville (Québec)  
Canada G6P 9G7  
Telephone: (819) 751-2440      Telefax: (819) 751-2434

**2. COMPOSITION / INFORMATION ON INGREDIENTS****Lactulose**

CAS Number : 4618-18-2  
Concentration : 634 – 700 g/l

**3. HAZARDS IDENTIFICATION**

Presents little hazard to human health and the environment.

**4. FIRST-AID MEASURES****4.1. Health effects****Inhalation**

- Negligible

**Eyes contact**

- Mechanical irritation from the particulates generated by the product.

**Skin contact**

- Negligible

**Ingestion**

- Abdominal cramps and diarrhea

**4.2. Inhalation**

Negligible

**Eyes contact**

Negligible

**Skin contact**

Negligible

**Ingestion**

***If the subject is completely conscious:***

- Rinse mouth and administer fresh water.

***If the subject is unconscious:***

- Not applicable

**5. FIRE-FIGHTING MEASURES****5.1. Suitable extinguishing media**

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

**5.2. Unsuitable extinguishing media**

- No restriction

**5.3. Special exposure hazards**

- Non-combustible

**5.4. Protective measures in case of intervention**

- The product does not require any special precautions

**6. ACCIDENTAL RELEASE MEASURES****6.1. Precautions**

- Follow the protective measures given in section 8.

**6.2. Cleanup methods**

- Collect the product with suitable means.

- Place everything into a closed, labeled container compatible with the product.

- Clean the area with large quantities of water.

- For disposal methods, refer to section 13.

**6.3. Precautions for protection of the environment**

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

**7. HANDLING AND STORAGE****7.1. Handling**

- Negligible

- 7.2. Storage**  
- Keep in original packaging, closed
- 7.3. Other precautions**  
- Follow the protective measures given in
- 7.4. Packaging**  
- HDPE

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

- 8.1. Engineering controls**  
- Follow the protective measures given in section 7.
- 8.2. Respiratory protection**  
- Wear appropriate NIOSH/MSHA-approved respirator.
- 8.3. Hand protection**  
- Negligible
- 8.4. Eye protection**  
- Wear protective goggles for all industrial operations.
- 8.5. Skin protection**  
- Negligible
- 8.6. Other precautions**  
- Negligible

## 9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1. General information**
- |                   |   |                      |
|-------------------|---|----------------------|
| <b>Appearance</b> | : | Viscous liquid       |
| <b>Color</b>      | : | Pale brownish-yellow |
| <b>Odor</b>       | : | Slightly sweet odor  |
- 9.2. Important health, safety and environment information**
- |  |   |   |
|--|---|---|
| <b>pH</b>  | : | from 3.5 to 7 at concentration 10%                            |
| <b>Change of state</b>                             | : | Melting point/range: > 169 °C<br>Boiling point/range: No data |
| <b>Flash point</b>                                 | : | Non-flammable   |
| <b>Flammability</b>                                | : | Non-flammable   |
| <b>Vapor/vapour pressure</b>                       | : | No data   |
| <b>Vapor/vapour density (air=1)</b>                | : | No data   |
| <b>Solubility</b>                                  | : | Soluble in water  |
| <b>Density</b>                                     | : | Specific gravity = 1.3 – 1.34                                 |
| <b>Explosive properties</b>                        | : | No data   |
| <b>Oxidising properties</b>                        | : | No data   |
| <b>Partition coefficient<br/>n-octanol / water</b> | : | No data   |

## 10. STABILITY AND REACTIVITY

- 10.1. Conditions to avoid**  
Negligible
- 10.2. Materials to avoid**  
Negligible
- 10.3. Hazardous decomposition products**  
Carbon monoxide

## 11. TOXICOLOGICAL INFORMATION

- 11.1. Toxicological datas**  
**Acute toxicity**  
- Oral route, LD 50, rat, 30 to 45 ml/kg
- 11.2. 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
- 11.3. Comments**  
- Not hazardous in normal conditions of handling and use

## 12. ECOLOGICAL INFORMATION

- 12.1 Ecotoxicity**  
**Acute ecotoxicity**  
- Fishes, Brachydanio rerio, LC 50, 96 hour(s), > 100 mg/l.  
- Crustaceans, Daphnia magna, EC 50, 48 hour(s), > 100 mg/l.
- 12.2 Mobility**  
- Water/soil.  
Result: considerable solubility and mobility.  
- Soil/sediments, log KOC = 0.4.  
Result: non-significant adsorption.
- 12.3 Abiotic degradation**  
- hydrolysis, degradation = 0 %, 2 year(s).  
Conditions: ambient temperature/slightly acid pH/concentrated solution  $\geq$  50%.  
**Biotic degradation**  
- Aerobic, test : ready biodegradability/closed bottle, degradation 65%, 28 day(s).  
Result: readily biodegradable.
- 12.4 Potential for bioaccumulation**  
-Bioconcentration : log PQ/W = -4.7.  
Result: improbable bioaccumulation.

**12.5 Comments**

- Product is not significantly hazardous for the aquatic environment.

**13. DISPOSAL CONSIDERATIONS****13.1. Waste treatment**

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

**13.2. Packaging treatment**

- Containers that cannot be cleaned must be treated as waste.

**14. TRANSPORT INFORMATION**

- Not subject

**15. REGULATORY INFORMATION****15.1. EEC Labeling**

Not dangerous according to Dir. 92/32/EEC.

**16. OTHER INFORMATION**

The information given corresponds to the current state of our knowledge and experience of the product.