

# SAFETY DATA SHEET

According to Directive 2001/58/EC

## LACTULOSE LIQUID 667 g/l

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

#### 1.1. Identification of the substance/preparation

Product name : LACTULOSE LIQUID 667 g/l  
Chemical Name : 4-O-beta-D-galactopyranosyl-D-fructose  
Commercial Product Name : Duphalac, Duphalac syrup, Bifiteral, Duphalac solution, Lactulose syrup  
Molecular formula : C<sub>12</sub>H<sub>22</sub>O<sub>11</sub>  
Molecular Weight : 342.3 g/mol

#### 1.2. Use of the Substance/Preparation

Recommended use : - Pharmaceuticals

#### 1.3. Company/Undertaking Identification

Address : SOLVAY PHARMACEUTICALS B.V.  
C.J. VAN HOUTENLAAN, 36  
NL- 1381 CP WEESP

Telephone : 31294477000

Telefax : 31294480253

#### 1.4. Emergency and contact telephone numbers

Emergency telephone number : +44(0)208 762 8322 [CareChem 24] (Europe)

Contact telephone number (product information): NL: +31-(0)-249 477 000 (Solvay Pharmaceuticals Weesp)

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Substance name (CAS-No. / EC-No. / Annex-1)	Concentration (W/W)	Classification	R-phrase(s)
Lactulose (4618-18-2 / 225-027-7 / Exempt or not available )	66.7 %		

### 3. HAZARDS IDENTIFICATION

Appearance : viscous liquid  
Colour : colourless  
Odour : no data available

- The preparation is non-dangerous in accordance with Directive 1999/45/EC.



## 4. FIRST AID MEASURES

### 4.1. Inhalation

- No hazards which require special first aid measures.

### 4.2. Eye contact

- Rinse thoroughly with plenty of water, also under the eyelids.

### 4.3. Skin contact

- Wash off with plenty of water.

### 4.4. Ingestion

- If a large amount is swallowed, get medical attention.

#### *If victim is conscious:*

- If swallowed, rinse mouth with water (only if the person is conscious).

#### *If victim is unconscious but breathing:*

- not applicable

## 5. FIRE-FIGHTING MEASURES

### 5.1. Suitable extinguishing media

- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

### 5.2. Extinguishing media which must not be used for safety reasons

- None.

### 5.3. Special exposure hazards in a fire

- Not combustible.

### 5.4. Special protective equipment for fire-fighters

- Fire fighters must wear fire resistant personnel protective equipment.
- In the event of fire, wear self-contained breathing apparatus.

### 5.5. Other information

- Cool containers / tanks with water spray.

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions

- Refer to protective measures listed in sections 7 and 8.

### 6.2. Environmental precautions

- Should not be released into the environment.

### 6.3. Methods for cleaning up

- Dam up.
- Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
- Prevent product from entering drains.
- Keep in properly labelled containers.
- Keep in suitable, closed containers for disposal.
- Treat recovered material as described in the section "Disposal considerations".
- Flush with plenty of water.



## 7. HANDLING AND STORAGE

### 7.1. Handling

- No special handling advice required.

### 7.2. Storage

- To maintain product quality, do not store in heat or direct sunlight.
- Store in original container.
- Keep container closed.
- Keep in a dry place.

### 7.3. Specific use(s)

- For further information, please contact: Supplier

### 7.4. Packaging material

- Polyethylene
- glass

### 7.5. Other information

- For personal protection see section 8.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1. Exposure Limit Values

#### Lactulose

- SAEL (Solvay Acceptable Exposure Limit)  
TWA = 10 mg/m<sup>3</sup>
- US. ACGIH Threshold Limit Values  
Remarks: none established

### 8.2. Exposure controls

- Refer to protective measures listed in sections 7 and 8.
- Provide appropriate exhaust ventilation at machinery.
- Apply technical measures to comply with the occupational exposure limits.

#### 8.2.1. Occupational exposure controls

##### 8.2.1.1. *Respiratory protection*

- No personal respiratory protective equipment normally required.

##### 8.2.1.2. *Hand protection*

- negligible

##### 8.2.1.3. *Eye protection*

- Chemical resistant goggles must be worn.

##### 8.2.1.4. *Skin and body protection*

- negligible

##### 8.2.1.5. *Hygiene measures*

- When using do not eat, drink or smoke.
- Handle in accordance with good industrial hygiene and safety practice.

#### 8.2.2. Environmental exposure controls

- Dispose of rinse water in accordance with local and national regulations.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. General Information (appearance, odour)



<b>Appearance</b>	: viscous liquid
<b>Colour</b>	: colourless
<b>Odour</b>	: no data available

## 9.2. Important health safety and environmental information

<b>pH</b>	: 3 - 7 <i>Concentration: 100 g/l</i> <i>Temperature: 25 °C</i>
<b>Boiling point/range</b>	: <i>Remarks: no data available</i>
<b>Flammability</b>	: <i>Remarks: The product is not flammable.</i>
<b>Explosive properties</b>	: <u><i>Explosion danger:</i></u> <i>Remarks: Not explosive</i>
<b>Vapour pressure</b>	: <i>Remarks: no data available</i>
<b>Relative density / Density</b>	: 1.3 - 1.34
<b>Solubility</b>	: Water > 685 g/l (Lactulose crystalline) <i>Temperature: 25 °C</i>
<b>Partition coefficient (n-octanol/water)</b>	: <u><i>log Pow:</i></u> -4.7 (Lactulose crystalline) <i>Method: calculated value</i>

## 9.3. Other data

<b>Melting point/range</b>	: > 169 °C
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## 10. STABILITY AND REACTIVITY

### 10.1. Stability

- Stable under recommended storage conditions.

### 10.2. Conditions to avoid

- none

### 10.3. Materials to avoid

- none

### 10.4. Hazardous decomposition products

- Carbon monoxide

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Toxicological data

#### **Acute oral toxicity**

- LD50, rat, 40 - 60 g/kg

#### **Chronic toxicity**

- Oral, Prolonged exposure, rat, NOEL: 20 g/kg
- Oral, Prolonged exposure, dog, Target Organs: gastro-intestinal system, LOEL (Lowest observable effect level): 5 g/kg

#### **Toxicity to reproduction**

- Animal testing did not show any effects on fertility.



**Teratogenicity**

- Did not show teratogenic effects in animal experiments.

**11.2. Health effects****Inhalation**

- No adverse effects are normally expected.

**Eye contact**

- No adverse effects are normally expected.

**Skin contact**

- No adverse effects are normally expected.

**Ingestion**

- No reported cases of intoxication in man.
- Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

**12. ECOLOGICAL INFORMATION****12.1. Ecotoxicity effects****Acute toxicity**

- Fishes, *Brachydanio rerio*, LC50, 96 h, > 100 mg/l (Lactulose crystalline)
- Crustaceans, *Daphnia magna*, EC50, 48 h, > 100 mg/l (Lactulose crystalline)

**Chronic toxicity**

- Algae, *Selenastrum capricornutum*, EC50, growth, 72 h, > 100 mg/l (Lactulose crystalline)

**12.2. Mobility****Water, Soil**

Remarks: considerable solubility and mobility

**Soil/sediments, log KOC:0.4**

Remarks: non-significant adsorption

**12.3. Persistence and degradability****Biodegradation**

- aerobic, Tested according to: Closed Bottle test, 65 %, 28 d  
Result: Readily biodegradable.

**12.4. Bioaccumulative potential**

- log Pow < 3  
Result: Does not bioaccumulate.

**12.5. Other adverse effects**

- no data available

**12.6. Possible hazards (summary)**

- Ecological injuries are not known or expected under normal use.

**13. DISPOSAL CONSIDERATIONS****13.1. Waste from residues / unused products**

- In accordance with local and national regulations.
- Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.

**13.2. Packaging treatment**

- Dispose of as unused product.
- Where possible recycling is preferred to disposal or incineration.



## 14. TRANSPORT INFORMATION

- Sea (IMO/IMDG)
- not regulated
- Air (ICAO/IATA)
- not regulated
- European Road/Rail (ADR/RID)
- not regulated

## 15. REGULATORY INFORMATION

### 15.1. EC Label

- Preparation non classified according to Directive 1999/45/EC.

### 15.2. Other regulations

- European Waste Catalogue, Decision (2000/532/EC), Hazardous waste, Waste codes should be assigned by the user based on the application for which the product was used., The following Waste Codes are only suggestions:
- 18 01 06 (Wastes from human health care/chemicals consisting of or containing dangerous substances)

## 16. OTHER INFORMATION

### 16.1. Administrative information

- General revision
- Distribute new edition to clients

This SDS is only intended for the indicated country to which it is applicable. The European SDS format compliant with the applicable European legislation is not intended for use nor distribution in countries outside the European Union with the exception of Norway and Switzerland. Safety datasheets applicable in other countries/regions are available upon request.

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 this case 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.

