

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 03.09.2013

Version number 1

Revision: 03.09.2013

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** Lactulose
- **Reference number:** Cat 210
- **CAS Number:**
4618-18-2
- **EC number:**
225-027-7
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Reference material for laboratory use only
- **Manufacturer/Supplier:**
British Pharmacopoeia Commission
MHRA
10 South Colonnade, Canary Wharf
London E14 4PU
United Kingdom

Tel : +44 (0)20 3080 6561
eMail: bpcrs@mhra.gov.uk
- **Further information obtainable from:** eMail: bpcrs@mhra.gov.uk
- **Emergency telephone number:** +44 (0) 20 3080 6561 (Monday - Friday: 8am - 5pm)

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified according to the CLP regulation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:** Not applicable.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Not applicable
- **Hazard pictograms** Not applicable
- **Signal word** Not applicable
- **Hazard statements** Not applicable
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization:** Substances
- **CAS No. Description**
4618-18-2 lactulose
- **Identification number(s)** -
- **EC number:** 225-027-7
- **RTECS:** LS6965000
- **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.

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- **After swallowing:** Rinse mouth. Do not induce vomiting.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
Store only in the original receptacle.
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** Lists used were valid at the time of SDS preparation.

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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Solid
Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range:	167-169 °C (Z)
Boiling point/Boiling range:	Not determined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

· Ignition temperature:

Decomposition temperature: Not determined.

· Self-igniting: Not determined.

· Danger of explosion: Not determined.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapour pressure: Not applicable.

Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.

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- | | |
|---------------------------------------------------|--------------------------------------------|
| · Solubility in / Miscibility with water: | Not determined. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |
| · Other information | No further relevant information available. |

10 Stability and reactivity

- **Reactivity** Stable under normal conditions.
- **Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**
Formation of toxic gases is possible during heating or in case of fire.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** Heat.
- **Incompatible materials:** Strong oxidizing agents.
- **Hazardous decomposition products:** Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values relevant for classification:		
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Oral	LD50	18160 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritating effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.
The substance is not subject to classification according to the latest version of the EU lists.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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· **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

14 Transport information

- | | |
|----------------------------------------------------------------------------------|------------------------------------------------------|
| · UN-Number | |
| · ADR, ADN, IMDG, IATA | Not applicable |
| · ADR, ADN, IMDG, IATA | Not applicable |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Not applicable |
| · Packing group | |
| · ADR, IMDG, IATA | Not applicable |
| · Environmental hazards: | |
| · Marine pollutant: | No
Yes (PP) |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · UN "Model Regulation": | - |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Philippines Inventory of Chemicals and Chemical Substances** Substance is not listed.
- **Australian Inventory of Chemical Substances** Substance is listed.
- **Standard for the Uniform Scheduling of Drugs and Poisons** Substance is not listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held

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responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

PP: Severe Marine Pollutant

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

· **Sources**

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.