

Safety data sheet
 according to UK REACH

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Version number 6.02 (replaces version 6.01)

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

- **1.1 Product identifier**
- **Trade name:** D(+)-Lactose monohydrate
- **Article number:** 1375
- **CAS Number:**
10039-26-6
- **EC number:**
200-559-2
- **Application of the substance / the mixture** Laboratory chemicals
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
 PANREAC QUIMICA S.L.U.
 C/Garraf 2
 Polígono Pla de la Bruguera
 E-08211 Castellar del Vallès (Barcelona)

Tel. (+34) 937 489 400
 Fax. (+34) 937 489 401
 e-mail: product.safety@itwreagents.com
- **Further information obtainable from:** email: product.safety@panreac.com
- **1.4 Emergency telephone number:**
 Single telephone number for emergency calls: 112 (EU)
 Tel.: (+34) 937 489 499

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
 The substance is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: D(+)-Lactose monohydrate

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SECTION 3: Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**
10039-26-6 D(+)-Lactose monohydrate
- **Identification number(s)**
- **EC number:** 200-559-2

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Immediately rinse with water.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water.
Seek medical treatment.
- **After swallowing:**
Rinse out mouth.
make victim drink water (maximum of 2 drinking glasses)
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
Water, CO2, foam, powder.
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
In case of fire, the following can be released:
Carbon monoxide and carbon dioxide
Non-combustible.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Do not inhale dust.
Ensure adequate ventilation
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

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· **6.3 Methods and material for containment and cleaning up:**

Pick up mechanically.
Avoid formation of dust.
Clean up affected area.

· **6.4 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.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** Provide suction extractors if dust is formed.

· **Information about fire - and explosion protection:** The product is not flammable.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** No special requirements.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** Keep container sealed.

· **Recommended storage temperature:** Room Temperature

· **Storage class:** 13

· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:** Not required.

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.

· **Respiratory protection:** Required when dusts are generated.

· **Recommended filter device for short term use:** Filter P1

· **Hand protection**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
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.

· **For the permanent contact gloves made of the following materials are suitable:**

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.11 mm

Value for the permeation: Level ≥ 480 min

· **As protection from splashes gloves made of the following materials are suitable:**

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.11 mm

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Value for the permeation: Level $\geq$ 480 min

- **Eye/face protection** Safety glasses
- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

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|---|------------------------------------|
| · Physical state | Solid |
| · Colour: | White |
| · Odour: | Odourless |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | 202 °C |
| · Boiling point or initial boiling point and boiling range | Undetermined. |
| · Flammability | Not determined.
Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | Not applicable. |
| · Decomposition temperature: | Not determined. |
| · pH | 4-6.5 |
| · Viscosity: | |
| · Kinematic viscosity | Not applicable. |
| · Dynamic: | Not applicable. |
| · Solubility | |
| · water at 20 °C: | 161 g/l |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | Not applicable. |
| · Density and/or relative density | |
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapour density | Not applicable. |

· 9.2 Other information

- | | |
|--|---|
| · Appearance: | |
| · Form: | Solid |
| · Important information on protection of health and environment, and on safety. | |
| · Ignition temperature: | Not determined. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Molecular weight | 360.32 g/mol |
| · Change in condition | |
| · Evaporation rate | Not applicable. |

· Information with regard to physical hazard classes

- | | |
|-------------------------------|------|
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |

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|---|------|
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
Quantitative data on the toxicological effect of this product are not available.

Components	Type	Value	Species
Oral	LD50	>10,000 mg/kg	(rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **After inhalation:** No irritant effect.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

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SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential**
Due to the distribution coefficient n-octanol/water an accumulation in organisms is not expected.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Do not allow product to reach ground water, water course or sewage system.
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Chemicals must be disposed of in compliance with the respective national regulations.
- **Uncleaned packaging:**
- **Recommendation:**
Disposal must be made according to official regulations.
Packagings that may not be cleansed are to be disposed of in the same manner as the product.

SECTION 14: Transport information

- | | |
|---|--|
| · 14.1 UN number or ID number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |

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· **UN "Model Regulation":** Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Poisons Act**
- **Regulated explosives precursors** Substance is not listed.
- **Regulated poisons** Substance is not listed.
- **Reportable explosives precursors** Substance is not listed.
- **Reportable poisons** Substance is not listed.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Abbreviations and acronyms:**
 - RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
 - ADR: Accord relatif au transport international 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
 - GHS: Globally Harmonised 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
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
- *** Data compared to the previous version altered.**

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