

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

- **1.1 Product identifier**
- **Trade name:** D-Lactose Anhydrous, USP/NF
- **Article number:** 199677
- **CAS Number:**
63-42-3
- **EC number:**
200-559-2
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Research use only.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
MP Biomedicals Europe
Parc d'Innovation BP 50067
Rue Geiler de Kaysersberg
Illkirch Cedex 67402
France
tel: +33 3.88.67.54.25
www.mpbio.com
- **Further information obtainable from:** Product safety department
- **1.4 Emergency telephone number:** :n° ORFILA" (01-45-42-59-59)

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 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.

SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
- **CAS No. Description**
63-42-3 D-Lactose Anhydrous
- **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:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **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:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** *No further relevant information available.*
- **5.3 Advice for firefighters**
- **Protective equipment:** *No special measures required.*

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** *Not required.*
- **6.2 Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.*
- **6.3 Methods and material for containment and cleaning up:** *Pick up mechanically.*
- **6.4 Reference to other sections**
No dangerous substances are released.
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** *No special measures required.*
- **Information about fire - and explosion protection:** *No special measures required.*
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:** *15 - 30 °C*
- **Requirements to be met by storerooms and receptacles:** *No special requirements.*
- **Information about storage in one common storage facility:** *Not required.*
- **7.3 Specific end use(s)** *No further relevant information available.*

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** *No further data; see item 7.*
- **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**
- **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.

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- **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:** Not required.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Powder

Colour: White

· Odour: Indeterminate

· Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range: 203,5 °C

Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Product is not flammable.

· Ignition temperature:

Decomposition temperature: Not determined.

· Self-igniting: Not determined.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined.

Upper: Not determined.

· Vapour pressure: Not applicable.

· Density at 20 °C: 1,53 g/cm³

· Relative density: Not determined.

· Vapour density: Not applicable.

· Evaporation rate: Not applicable.

· Solubility in / Miscibility with -

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

Dynamic: Not applicable.

Kinematic: Not applicable.

· 9.2 Other information: No further relevant information available.

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.

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- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

Oral	LD50	10000 mg/kg (rat)
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- **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.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

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** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

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|---------------------------------------|---------------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Not regulated |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Not regulated |

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· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	<i>Not regulated</i>
· 14.4 Packing group	
· ADR, IMDG, IATA	<i>Not regulated</i>
· 14.5 Environmental hazards:	
· Marine pollutant:	<i>No</i>
· 14.6 Special precautions for user	<i>Not applicable.</i>
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>Not regulated</i>

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- *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.

- **Department issuing MSDS:** *Product safety department*
- **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*
 - 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*