

SAFETY DATA SHEET
PEARLITOL® 200 SD

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

1.1 Product identifier:

Product name: PEARLITOL® 200 SD - MANNITOL EP-USP

UFI Number: Not applicable.
Chemical name: D-Mannitol
DUIN Number : Exempted (Annex IV).
CAS-No.: 69-65-8
EC No.: 200-711-8

1.2 Relevant identified uses of the substance or mixture and uses advised against:

| Identified uses: | Uses advised against: |
|--------------------------|-----------------------|
| Pharmaceuticals. , Food. | No data available. |

1.3 Details of the supplier of the safety data sheet:

Supplier:

ROQUETTE FRERES
1 Rue de la Haute Loge
62136 LESTREM - France

Telephone: +33 3 21 63 36 00
Fax: +33 3 21 63 38 50
E-mail: sds@roquette.com

1.4 Emergency telephone number:

NPIS (24/24) : 844 892 0111

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

The product has not been classified as dangerous according to the legislation in force : CLP Regulation (EC) No 1272/2008.

2.2 Label elements: Not applicable

2.3 Other hazards: May form explosible dust-air mixture if dispersed in the air
Not fulfilling PBT (persistent/bioaccumulative/toxic) criteria
Not fulfilling vPvB (very persistent/very bioaccumulative) criteria

SECTION 3: Composition/information on ingredients

3.1 Substance:

| Chemical name | Concentration | CAS-No. | EC No. | DUIN Number : |
|---------------|---------------|---------|-----------|----------------------|
| D-Mannitol | >=99% | 69-65-8 | 200-711-8 | Exempted (Annex IV). |

SECTION 4: First aid measures

4.1 Description of first aid measures:

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| Inhalation: | Move the exposed person to fresh air at once. Get medical attention if any discomfort continues. |
| Eye contact: | Flush thoroughly with water for at least 15 minutes. Get medical assistance. |
| Skin contact: | Wash with soap and water. |
| Ingestion: | Product not hazardous when ingested. Ingestion may cause: Diarrhoea. Get medical attention if any discomfort continues. |

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| 4.2 Most important symptoms and effects, both acute and delayed: | Ingestion may cause: Diarrhoea. Dust may irritate the eyes and the respiratory system. |
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4.3 Indication of any immediate medical attention and special treatment needed:

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| Treatment: | Treat symptomatically. |
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SECTION 5: Firefighting measures

5.1 Extinguishing media:

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| Suitable extinguishing media: | Water spray. |
| Unsuitable extinguishing media: | Dry chemicals or foams. Straight Streams of Water |

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| 5.2 Special hazards arising from the substance or mixture: | Fire or excessive heat may produce hazardous decomposition products. See Section 10. Combustible dusts : may form an explosible mixture in the air. |
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5.3 Advice for firefighters:

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| Special Fire Fighting Procedures: | Prevent dust cloud. Do not use water jet as an extinguisher, as this will spread the fire. |
| Special protective equipment for fire-fighters: | Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. |

SECTION 6: Accidental release measures

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| 6.1 Personal precautions, protective equipment and emergency procedures: | See Section 8 of the SDS for Personal Protective Equipment. |
| 6.2 Environmental precautions: | Avoid release to the environment. |
| 6.3 Methods and material for containment and cleaning up: | Remove material, as much as possible, using mechanical equipment. Prevent dust cloud. Collect and dispose of spillage as indicated in section 13 of the SDS. |

6.4 Reference to other sections:

For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1 Precautions for safe handling:

See Section 8 of the SDS for Personal Protective Equipment.

7.2 Conditions for safe storage, including any incompatibilities:

Preserve in well-closed original packing, Storage requirements not specified. Avoid contact with oxidizing agents.

7.3 Specific end use(s):

Pharmaceuticals., Food.,

SECTION 8: Exposure controls/personal protection

8.1 Control parameters:

Occupational exposure limits:

This product does not contain any components >1% with specific occupational exposure limits.

| Chemical name | Type | Exposure Limit Values | Source |
|-------------------------|------|-----------------------|--|
| Dust - Inhalable dust. | TWA | 10 mg/m ³ | UK. EH40 Workplace Exposure Limits (WELs) (2018) |
| Dust - Respirable dust. | TWA | 4 mg/m ³ | UK. EH40 Workplace Exposure Limits (WELs) (2018) |

8.2 Exposure controls:

Appropriate engineering controls:

Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of dust.

Individual protection measures, such as personal protective equipment:

Eye/face protection:

Wear dust-proof safety goggles where there is a risk of eyes contact. (EN 166)

Skin protection:

Hand Protection:

No special precautions.

Other:

Wear suitable protective clothing.

Respiratory Protection:

In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P1). (EN 143)

Hygiene measures:

Handle the product in accordance with the good hygiene practices and safety instructions.

Environmental exposure controls:

Avoid discharge to the aquatic environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

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| Physical State: | solid |
| Form: | Powder |
| Color: | White |
| Odor: | Odorless |
| Odor Threshold: | No data available. |
| Melting Point: | ~ 166 °C |
| Boiling Point: | Not Applicable |
| Flash Point: | Not Applicable |
| Decomposition Temperature: | > 300 °C |
| pH: | ~ 5.3 at 20 % w/w in water |
| Flammability (solid, gas): | NC: Not Classified |
| Solubility in Water: | ~ 250 g/l at 20 °C |
| Partition coefficient (n-octanol/water): | -3.10 - Literature Reference - |
| Vapor pressure: | Not Applicable |
| Relative density: | ~ 0.5 |
| Vapor density (air=1): | Not Applicable |

9.2 Other information:

9.2.1 Information with regard to physical hazard classes:

No data available.

9.2.2 Other safety characteristics:

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| Formation of explosible dust/air mixtures: | - INERIS - Data from similar product. |
| MIT (Minimum ignition temperature): | MITc (cloud) : ~ 420 °C (EN 50281-2-1 / ASTM E1491) |
| MIE (Minimum Ignition Energy): | > 1,000 mJ (EN 13821) Very insensitive to the risk of inflammation by an electrostatic discharge. |
| (dP/dt)_{max} (Maximum Rate of explosion Pressure rise): | ~ 335 bar/s (EN 14034-2 / ASTM E1226) |
| P_{max} (Maximum Explosion OverPressure) ±10%: | ~ 8.9 bar (EN 14034-1 / ASTM E1226) |
| K_{st} value (±20%): | ~ 96 bar·m/s (EN 14034-2 / ASTM E1226) |
| Dust Explosion Class: | st 1 (VDI 3673) |
| Volume resistivity: | > 10 ⁹ Ω·cm (IEC 61241-2-2 / Group IIIB non-conductive dust.) |
| Moisture: | ~ 0.2 % (ISO 589) |
| M_v (Median value): | ~ 118 µm (ISO 13320) |
| Other Data: | MEC (Minimum Explosible Concentration) : 30-60 g/m ³ (EN 14034-3 / ASTM E1515) |
| Oxidizing properties | NC: Not Classified |
| Evaporation Rate: | Not Applicable |
| Conductivity: | 1.7 µS/cm (at 20%) |

The data reported in this section does not take the place of specifications.

SECTION 10: Stability and reactivity

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| 10.1 Reactivity: | Oxidizing agents. |
| 10.2 Chemical stability: | Material is stable under normal conditions. |
| 10.3 Possibility of hazardous reactions: | No hazardous reactions under ordinary conditions of use and storage. |

10.4 Conditions to avoid:

Prevent dust cloud. Dust clouds may be explosive under certain conditions. Avoid dust close to ignition sources.

10.5 Incompatible materials:

Strong oxidizing substances. Strong Acids, Strong Bases

10.6 Hazardous decomposition products:

Carbon Monoxide. Carbon Dioxide.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation EC 1272/2008:

Acute toxicity :

| Test / Substance | Species | Type / Result | Exposure | Remarks |
|------------------|---------|---|----------|--------------------------|
| D-Mannitol | Mouse | LD50 - Oral : 22 g/kg Not classified | | - Literature Reference - |
| D-Mannitol | Rat | LD50 - Oral : 13,5 g/kg Not classified | | - Literature Reference - |
| D-Mannitol | Rat | LD50 - Intravenous : 9,69 g/kg Not classified | | - Literature Reference - |
| D-Mannitol | Mouse | LD50 - Intravenous : 7,47 g/kg Not classified | | - Literature Reference - |
| D-Mannitol | Mouse | LD50 - Intraperitoneal : 14 g/kg Not classified | | - Literature Reference - |

Skin irritation. :

| Test / Substance | Species | Result | Exposure | Remarks |
|------------------------|----------|----------------|----------|-------------------|
| OECD 439 D-Mannitol | In vitro | Not Irritating | | - Internal data - |

Serious eye irritation :

| Test / Substance | Species | Result | Exposure | Remarks |
|------------------------|----------------|-----------------|----------|-------------------|
| OECD 437 D-Mannitol | Bovine cornea. | Not classified. | | - Internal data - |

Sensitization :

| Test / Substance | Type | Species | Result | Remarks |
|-------------------------|------|----------|------------------------|-------------------|
| OECD 442E D-Mannitol | | In vitro | Not a skin sensitizer. | - Internal data - |

Repeated dose toxicity :

| Test / Substance | Species | Result | Exposure | Remarks |
|-----------------------------------|---------|---|-------------|--------------------------|
| Experimental result D-Mannitol | Rat | No data on possible toxicity effects have been found. | 94 Week(s). | - Literature Reference - |

Mutagenesis :

| Test / Substance | Type | Species | Result | Remarks |
|-------------------------------|----------|----------------|----------|--------------------------|
| OECD 471 (Ames) D-Mannitol | In vitro | S. typhimurium | Negative | - Literature Reference - |

Carcinogenicity :

| Test / Substance | Species | Route of Exposure / Exposure | Result | Remarks |
|------------------|---------|------------------------------|----------|--------------------------|
| D-Mannitol | Rat | Oral 103 Week(s). | Negative | - Literature Reference - |
| D-Mannitol | Mouse | Oral 103 Week(s). | Negative | - Literature Reference - |

Reproductive toxicity :

| Test / Substance | Species | Route of Exposure / Exposure | Result | Remarks |
|------------------|---------|------------------------------|----------|--------------------------|
| D-Mannitol | Rat | Oral 10 day(s) | Negative | - Literature Reference - |

11.2 Information on other hazards: No data available.
Remarks: The ingredients of this product are not classified as carcinogenic by the ACGIH, the CIRC, the OSHA or the NTP.

SECTION 12: Ecological information

12.1 Toxicity:

Acute toxicity:

| Test / Substance | Species | Type/Result | Exposure | Remarks |
|------------------------|-------------------------|-------------------------|----------|-------------------|
| OECD 201 D-Mannitol | Desmodesmus subspicatus | NOEC : \geq 99.4 mg/l | 72 h | - Internal data - |
| OECD 202 D-Mannitol | Daphnia magna | NOEC : \geq 99.4 mg/l | 48 h | - Internal data - |
| OECD 202 D-Mannitol | Daphnia magna | EC50 : \geq 99.4 mg/l | 48 h | - Internal data - |

Chronic Toxicity: No data available.

12.2 Persistence and degradability:

| Test / Substance | Result | Remarks |
|-------------------------|---|-------------------|
| OECD 301b D-Mannitol | 95.1 % / 28 d Ready Biodegradability | - Internal data - |

12.3 Bioaccumulative potential:

| Test / Substance | Log Pow (n-Octanol/Water Partition Coefficient) | Bioconcentration Factor (BCF) / Bioaccumulation | Remarks |
|------------------|---|---|--|
| D-Mannitol | -3.10 | ~ 1 | Potential to bioaccumulate is low. - Literature Reference - |

12.4 Mobility in soil:

| Test / Substance | Medium | Organic Carbon Partition Coefficient (Koc) | Remarks |
|------------------|--------|--|---|
| D-Mannitol | soil | ~ 5 | This material is readily biodegraded and is not likely to bioconcentrate. - Literature Reference - |

12.5 Results of PBT and vPvB assessment: Exempted
12.6 Endocrine disrupting properties: No data available.

12.7 Other adverse effects: None known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Product: Dispose of waste in an appropriate authorized treatment facility in accordance with regulations in force and product characteristics at time of disposal.

Packaging material: Single use packaging. Collect for salvage or disposal.

SECTION 14: Transport information

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|--|-------------------------|
| 14.1 UN number: | Not applicable. |
| 14.2 UN proper shipping name: | Not applicable. |
| 14.3 Transport hazard class(es): | Not applicable. |
| 14.4 Packing group: | Not applicable. |
| 14.5 Environmental hazards: | Not regulated. |
| 14.6 Special precautions for user: | No special precautions. |
| 14.7 Maritime transport in bulk according to IMO instruments: | Not applicable. |

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

EU.REACH Article 59, candidate List of Substances of Very High Concern (SVHC).
Not listed

Regulation (EC) No. 1907/2006 Annex XVII Substances subject to restriction on marketing and use
Not Applicable

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorisation, as amended
Not Applicable

Turkey. KKDİK Regulation (Turkey REACH)
Exempted ANNEX IV

REGULATION (EU) 2017/542 (CLP Annex VIII) :harmonised information relating to emergency health response and preventative measures.
UFI Number: Not Applicable

REGULATION (EU) 2019/1148 on the marketing and use of explosives precursors.
Not Applicable

International Inventories :

| | |
|---|---------|
| Australia. Inventory of Chemical Substances (AICS): | Listed. |
| Canada. Canadian Environmental Protection Act (CEPA). Domestic Substances List (DSL): | Listed. |
| China. Inventory of Existing Chemical Substances (IECSC): | Listed. |
| EU. European Inventory of Existing Commercial Chemical Substances (EINECS): | Listed. |
| Japan. Inventory of Existing & New Chemical Substances (ENCS): | Listed. |
| Japan. Industrial Safety & Health Law (ISHL): | Listed. |
| Japan. Pharmacopoeia Listing: | Listed. |
| Korea. Existing Chemicals Inventory (KECI): | Listed. |
| Mexico. National Inventory of Chemical Substances (INSQ): | Listed. |
| New Zealand. Inventory of Chemicals (NZIoC): | Listed. |
| Philippines. Inventory of Chemicals and Chemical Substances (PICCS): | Listed. |
| Taiwan. Existing Chemicals Inventory (TCSI): | Listed. |
| Thailand. Existing Chemicals Inventory from FDA (TECI): | Listed. |
| US. Toxic Substances Control Act (TSCA): | Listed. |
| Vietnam. National Chemical Inventory: | Listed. |

This Safety Data Sheet conforms to SCHEDULE 3 / Part 1 / annex II of regulation (GB)2019 n°758.

15.2 Chemical safety assessment: Exempted

SECTION 16: Other information

Revision Information: 10/25/2021

Key literature references and sources for data: ToxNet Database.
ECHA registered substances database. HSDB Database.
NTP: US. National Toxicology Program (NTP) Report on Carcinogens

Other information: Updated version of this document is available at :<https://www.roquette.com/site-search#documents>

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Abbreviations and acronyms used in the SDS.:

LD50: lethal dose 50%
CAS: Chemical Abstracts Service (division of the American Chemical Society)
CLP : Classification, Labelling and Packaging (Reg. EC 1272/2008).
PBT: Persistent, Bioaccumulative and Toxic
REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals.
vPvB: very persistent and very bioaccumulative substance.

Disclaimer: The information provided in this Safety Data Sheet (SDS) relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.
The information given is designed only as a guidance and is not to be considered a warranty or quality specification.
All information and instructions provided in this SDS are based on the current state of our knowledge at the latest revision date indicated.