

SAFETY DATA SHEET
PEARLITOL® 25C

SECTION 1 : Chemical product and company identification

1.1 Product identifier:

Product name: PEARLITOL® 25C - MANNITOL EP-USP

Chemical name: D-Mannitol
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

National Supplier:

Roquette China Co. Ltd
No.23 Zhen Xing Road, Song Tiao Industrial area,
Lianyungang Economic & Technical Development
Zone
222047 LIANYUNGANG, Jiangsu - China

Telephone: +86 518 8552 5588 / 8573 0000
Fax: +86 518 8557 9240

1.4 Emergency telephone number:

National Poison Control Center : +86-10-83132345 (24/24)

SECTION 2 : Hazard overview

2.1 Classification of the substance or mixture:

The product has not been classified as dangerous according to GHS.

2.2 Label elements: Not applicable

2.3 Other hazards: May form explosible dust-air mixture if airborne above the Minimum Explosive Concentration.

SECTION 3: Composition/information on ingredients

3.1 Substance:

Chemical name	Concentration	CAS-No.
D-Mannitol	>=99%	69-65-8

SECTION 4: First aid measures

4.1 Description of first aid measures:

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.

4.2 Most important symptoms and effects, both acute and delayed: Ingestion may cause: Diarrhoea. Dust may irritate the eyes and the respiratory system.

4.3 Indication of any immediate medical attention and special treatment needed:

Treatment: Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media:

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

5.2 Special hazards arising from the substance or mixture: Fire or excessive heat may produce hazardous substances. Combustible dusts : may form an explosible mixture in the air. See Section 10.

5.3 Advice for firefighters:

Special Fire Fighting Procedures:	Avoid dust cloud to prevent explosion risk. Do not use water jet as an extinguisher, as this would 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

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. Avoid dust cloud to prevent explosion risk. 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. See Section 5 of the SDS for prevention of combustible dust risk.

7.2 Conditions for safe storage, including any incompatibilities:

Keep containers tightly closed. Store in original container. 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 - Total dust.	TWA	8 mg/m ³	China. OELs (Occupational Exposure Limits for Hazardous Agents in the Workplace) (GBZ 2.1) (07 2024)

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.

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).

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:

Physical State:

solid

Form:

Powder

Color:	White
Odor:	Odorless
pH:	~ 5.4 at 20 % w/w in water
Melting Point:	~ 166 °C
Boiling Point:	Not applicable or not available
Flash Point:	> 150 °C
Vapor pressure:	Not Applicable
Vapor density (air=1):	Not Applicable
Relative density:	~ 0.45
Solubility in Water:	~ 250 g/l at 20 °C
Partition coefficient (n-octanol/water):	-3.10 - Literature Reference -
Decomposition Temperature:	> 300 °C
Explosive properties: - INERIS -	
MIT (Minimum ignition temperature):	MITc (cloud) : ~ 400 °C (EN 50281-2-1 / ASTM E1491) TDA (Differential Thermal Analysis), Δt : ~ 220 °C (EN 50281-2-1 / ASTM E1491)
MIE (Minimum Ignition Energy):	~ 21 mJ (EN 13821 / ASTM E2019, With Inductance)
(dP/dt)max (Maximum Rate of explosion Pressure rise):	~ 635 bar/s (EN 14034-2 / ASTM E1226)
Pmax (Maximum Explosion OverPressure) ±10%:	~ 8.1 bar (EN 14034-1 / ASTM E1226)
Kst value (±20%):	~ 172 barm/s (EN 14034-2 / ASTM E1226)
Dust Explosion Class:	st 1 (VDI 3673)
Volume resistivity:	>10 ⁹ Ω.m (IEC 61241-2-2 / Group IIIB non-conductive dust.)
Moisture:	~ 0.14 % (ISO 589)
Mv (Median value):	~ 31 μm (ISO 13320)
Other Data:	MEC (Minimum Explosible Concentration) : 30-60 g/m ³ (EN 14034-3 ASTM E1515)

9.2 Other information:

Conductivity: ~ 1.1 μS/cm (at 20% w/w in water)

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

SECTION 10: Stability and reactivity

10.1 Reactivity:	No data available.
10.2 Chemical stability:	No data available.
10.3 Possibility of hazardous reactions:	No data available.
10.4 Conditions to avoid:	Avoid dust cloud to prevent explosion risk. Dust clouds may explode 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 toxicological effects:

Acute toxicity :

Test / Substance	Species	Type / Result	Exposure	Remarks
D-Mannitol	Mouse	LD50 - Oral 22g/kg Not classified		- Literature Reference -
D-Mannitol	Rat	LD50 - Oral 13,5g/kg Not classified		- Literature Reference -
D-Mannitol	Rat	LD50 - Intravenous 9,69g/kg Not classified		- Literature Reference -
D-Mannitol	Mouse	LD50 - Intravenous 7,47g/kg Not classified		- Literature Reference -
D-Mannitol	Mouse	LD50 - Intraperitoneal 14g/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 : No data available.

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 -

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	Desmodemus subspicatus	NOEC : >= 99.4 mg/l	72 h	- Internal data -
OECD 202 D-Mannitol	Daphnia magna	NOEC : >= 99.4 mg/l	48 h	- Internal data -
OECD 202 D-Mannitol	Daphnia magna	EC50 : >= 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 Other adverse effects: No data available.

SECTION 13: Disposal

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

This material is not subject to transport regulations (IMDG, ICAO/IATA, ADR/RID, ADN).

SECTION 15: Regulatory information

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

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 (NCI):	Listed.

This Safety Data Sheet is in conformity with the chinese standard GB/T 17519-2013

SECTION 16: Other information

Revision Information: Not relevant.

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>

Abbreviations and acronyms used in the SDS.:

LD50: lethal dose 50%
CAS: Chemical Abstracts Service (division of the American Chemical Society)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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.