

SAFETY DATA SHEET
PEARLITOL® CR H

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

1.1 Product identifier:

Product name: PEARLITOL® CR H - HYPROMELLOSE-MANNITOL

UFI Number: Not applicable

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

Identified uses:	Uses advised against:
Pharmaceuticals.	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:

+33 3 21 63 36 00

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 airborne above the Minimum Explosive Concentration., See Section 9.2.2 for more information.

Not fulfilling PBT (persistent/bioaccumulative/toxic) criteria

Not fulfilling vPvB (very persistent/very bioaccumulative) criteria

SECTION 3: Composition/information on ingredients

3.2 Mixture: Mixture not classified according to GHS / CLP regulations.

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. See Section 10.
Combustible dusts : may form an explosible mixture in the air.

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.,

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.	MAK	4 mg/m ³	Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG) (2019)
Dust - Respirable dust.	MAK	0,3 mg/m ³	Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG) (2019)
Dust - Inhalable dust.	AGW	10 mg/m ³	Germany. TRGS 900, Limit Values in the Ambient Air at the Workplace (2019)
Dust - Respirable dust.	AGW	1,25 mg/m ³	Germany. TRGS 900, Limit Values in the Ambient Air at the Workplace (2019)

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:

Physical State:	solid
Form:	Powder
Water, moisture:	~ 5 %
Color:	Off-white
Odor:	Odorless
Odor Threshold:	No data available.
Melting Point:	No data available.
Boiling Point:	Not applicable or not available
Flash Point:	Not applicable or not available
pH:	5 at 10 % w/w in water
Flammability (solid, gas):	NC: Not Classified
Solubility in Water:	The product is partly soluble in water.
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:

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)
Pmax (Maximum Explosion OverPressure) ±10%:	~ 8,9 bar (EN 14034-1 / ASTM E1226)
Kst value (±20%):	~ 96 barm/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)
Mv (Median value):	~ 118 µm (ISO 13320)
Other Data:	MEC (Minimum Explosible Concentration) : 30-60 g/m ³ (EN 14034-3 / ASTM E1515)
Evaporation Rate:	Not Applicable

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

SECTION 10: Stability and reactivity

- 10.1 Reactivity:** Strong 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:** 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 hazard classes as defined in Regulation EC 1272/2008:** No data available.
- 11.2 Information on other hazards:** No data available.

SECTION 12: Ecological information

- 12.1 Toxicity:** No data available.
- 12.2 Persistence and degradability:** No data available.
- 12.3 Bioaccumulative potential:**
- 12.4 Mobility in soil:** No data available.
- 12.5 Results of PBT and vPvB assessment:** No data available.
- 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

- 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

Germany. Administrative Regulation under the Federal Water Act on the Classification of Water-Endangering Substances in Water-Endangering Classes (AWsV) :
Water Hazard Class (WGK): WGK 1: slightly water-endangering.(kennnummer:8 299)

This Safety Data Sheet is not mandatory according to the requirements of regulation (EC) N°1907/2006 (REACH) article 31 and is provided for information.

15.2 Chemical safety assessment: Exempted

SECTION 16: Other information

Revision Information: 02.03.2023

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.