

SAFETY DATA SHEET

KLEPTOSE® HPB PARENTERAL GRADE EP-USP

SECTION 1 : Identification

1.1 Product identifier:

Product name: KLEPTOSE® HPB PARENTERAL GRADE EP-USP

Synonyms: HYDROXYPROPYLBETADEX is a partially substituted poly (hydroxypropyl) ether

Chemical name: β -Cyclodextrin, 2-hydroxypropyl ethers

CAS-No.: 128446-35-5

EC No.: 420-920-1

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

Identified uses:	Uses advised against:
Pharmaceuticals.; PC 39 : Cosmetics, personal care products.	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:

World directory of poisons centres : http://www.who.int/gho/phe/chemical_safety/poisons_centres/en/

SECTION 2: Hazards identification

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: Dust may form an explosive mixture in the atmosphere.

SECTION 3: Composition/information on ingredients

3.1 Substance:

Chemical name	Concentration	CAS-No.
β -Cyclodextrin, 2-hydroxypropyl ethers	$\geq 97\%$	128446-35-5

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. If irritation occurs, get medical assistance.

Skin contact: Wash with soap and water.

Ingestion: Product not hazardous when ingested.

4.2 Most important symptoms and effects, both acute and delayed: No information about adverse effects due to exposure.

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

Treatment: No special precautions.

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 decomposition products. Dust may form an explosive mixture in the atmosphere. See Section 10.

5.3 Advice for firefighters:

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

6.1 Personal precautions, protective equipment and emergency procedures: See Section 8 of the SDS for Personal Protective Equipment.

6.2 Environmental precautions: Not regarded as dangerous for 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.

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:

Keep away from moisture. Store in original tightly closed container.

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.

8.2 Appropriate engineering controls:

Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded.

8.3 Individual protection measures, such as personal protective equipment:

Eye/face protection:	Wear dust-resistant safety glasses where there is danger of eye 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.

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:	0,55 at 2 %
Melting Point:	No data available.
Boiling Point:	Not Applicable
Flash Point:	Not Applicable
Vapor pressure:	Not Applicable
Vapor density (air=1):	Not Applicable
Relative density:	~ 0,44
Solubility in Water:	> 450 g/l at 20 °C

Explosive properties: - INERIS -Data from similar product.

Ignition Temperature:	~ 380 °C MIT in Cloud.
MIE (Minimum Ignition Energy):	~ 19 mJ (EN 13821) Very sensitive to ignition by an electrostatic phenomenon.
dP/dtmax (Maximum Rate of explosion Pressure rise):	~ 810 bar/s (EN 14034-2)
Pmax (Maximum Explosion OverPressure) ±10%:	~ 8,9 bar (EN 14034-1)
Kst value (±20%):	~ 219 barm/s (EN 14034-2)
Dust Explosion Class:	st 2 (VDI 3673)
Volume resistivity:	> 10 ⁹ Ω.m (IEC 61241-2-2 / Group IIIB non-conductive dust.)
Moisture:	~ 2,7 % (ISO 589)
Particle characteristics:	~ 37,5 µm (NFX 11-666)
Other Data:	LEL (Lower Explosion limit) : 30-60 g/m3

9.2 Other information:

Conductivity: 4,8 µS/cm (at 10%)

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

SECTION 10: Stability and reactivity

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.
10.6 Hazardous decomposition products:	Carbon Dioxide. Carbon Monoxide.

SECTION 11: Toxicological information

11.1 Information on toxicological effects:

Acute toxicity :

Test / Substance	Species	Type / Result	Exposure	Remarks
Other Guideline.	Mouse	LD50 - Intravenous >5000mg/kg No treatment related effects.		- Internal data -
EU B2	Rat	LC50 - Inhalation > 2,52 mg/l No treatment related effects.	4 h	- Internal data -

Skin irritation. :

Test / Substance	Species	Result	Exposure	Remarks
EU B4	Rabbit	Not Irritating	23 h	- Internal data -

Serious eye irritation :

Test / Substance	Species	Result	Exposure	Remarks
EU B5	Rabbit	Not Irritating		- Internal data -

Sensitization :

Test / Substance	Type	Species	Result	Remarks
AFNOR T03-300	In vivo	Guinea Pig	Non-Sensitising	- Internal data -

Repeated dose toxicity :

Test / Substance	Species	Result	Exposure	Remarks
OECD 452	Rat	NOAEL - 500 mg/kg		- Internal data -

Mutagenesis :

Test / Substance	Type	Species	Result	Remarks
OECD 471 (Ames)	In vitro	S. typhimurium	Negative	- Internal data -
EU B10	In vitro	Human lymphocytes.	Negative	- Internal data -
OECD 482	In vitro	Rat hepatocytes	Negative	- Internal data -
EU B12	In vivo	Mouse	Negative	- Internal data -

Carcinogenicity: No data available.

Reproductive toxicity: No data available.

SECTION 12: Ecological information

12.1 Toxicity:

Acute toxicity:

Test / Substance	Species	Type/Result	Exposure	Remarks
OECD 203	Lepomis macrochirus	LC50 : >1000 mg/l Not classified	96 h	- Internal data -
OECD 202	Daphnia magna	EC50 : >1000 mg/l Not classified	48 h	- Internal data -
OECD 201	Pseudokirchneriella subcapitata	>1000 mg/l Not classified	72 h	- Internal data -

Chronic Toxicity: No data available.

12.2 Persistence and degradability:

Test / Substance	Result	Remarks
OECD 301b	13 % / 28 d The product is not readily biodegradable.	- Internal data -

12.3 Bioaccumulative potential: No data available on bioaccumulation.

12.4 Mobility in soil: No data available.

12.5 Other adverse effects: None known.

SECTION 13: Disposal considerations

13.1 Disposal methods:

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

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

SECTION 14: Transport information

14.1 - 14.4 This material is not subject to transport regulations (IMDG, ICAO/IATA, ADR/RID, ADN).

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:

International Inventories :

Australia. Inventory of Chemical Substances (AICS):	Listed.
Canada. Canadian Environmental Protection Act (CEPA). Non-Domestic Substances List (NDSL):	Listed.
China. Inventory of Existing Chemical Substances (IECSC):	Listed.
Korea. Existing Chemicals Inventory (KECI):	Listed.
New Zealand. Inventory of Chemicals (NZIoC):	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 is in conformity with appendix 4 of the GHS (Globally Harmonised System of Classification and Labelling of Chemicals).

SECTION 16: Other information

Revision Information: Not relevant.

Key literature references and sources for data: REACH registration dossier:
<https://echa.europa.eu/registration-dossier/-/registered-dossier/14017>

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

Abbreviations and acronyms used in the SDS.:

CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50 : lethal concentration 50%
EC50 : The effective concentration of substance that causes 50% of the maximum response.
LD50: lethal dose 50%
NOAEL : No Observed Adverse Effect Level
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
OECD : Organisation for Economic Cooperation and Development

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.

