

SAFETY DATA SHEET

PentaHibe 40 ml, 40% Pentaisomaltose Sterile Solution

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

1.1. Product identifier

Trade name

PentaHibe 40 ml, 40% Pentaisomaltose Sterile Solution

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

Relevant identified uses of the substance or mixture

Cryopreservation

Uses advised against

No special.

1.3. Details of the supplier of the safety data sheet

Company and address

Pharmacosmos A/S

Roervangsvej 30

4300 Holbaek

Denmark

T: +45 5948 5959

F: +45 5948 5960

Contact person

Lise Larsen

E-mail

info@pharmacosmos.com

Revision

9/13/2022

SDS Version

1.0

1.4. Emergency telephone number

Contact the poison hotline: +45 82 12 12 12 (24 hour service)

See section 4 "First aid measures".

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified according to Regulation (EC) No. 1272/2008 (CLP).

2.2. Label elements

Hazard pictogram(s)

Not applicable.

Signal word

Not applicable.

Hazard statement(s)

Not applicable.

Safety statement(s)

General

-

Prevention

-

Response

-

Storage

-

Disposal

-

Hazardous substances

No special.

Additional labelling

Not applicable.

2.3. Other hazards

Additional warnings

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

This product does not contain any substances considered to be endocrine disruptors in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

| Product/substance | Identifiers | % w/w | Classification | Note |
|---------------------------|-------------|----------|----------------|------|
| Water For Injection (WFI) | CAS No.: | 60-70% | | |
| | EC No.: | | | |
| | REACH: | | | |
| | Index No.: | | | |
| Pentaisomaltose | CAS No.: | 32 - 37% | | |
| | EC No.: | | | |
| | REACH: | | | |
| | Index No.: | | | |

See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

-

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.

Inhalation

Upon breathing difficulties or irritation of the respiratory tract: Bring the person into fresh air and stay with him/her.

Skin contact

Upon irritation: rinse with water. In the event of continued irritation, seek medical assistance.

Eye contact

Upon irritation of the eye: Remove contact lenses. Flush eyes with plenty of water or salt water (20-30°C) and continue until irritation stops.

Ingestion

Provide plenty of water for the person to drink and stay with him/her. In case of malaise, seek medical advice immediately and bring the safety data sheet or label from the product. Do not induce vomiting, unless recommended by the doctor. Have the victim lean forward with head down to avoid inhalation of- or choking on vomited material.

Burns

Not applicable.

4.2. Most important symptoms and effects, both acute and delayed

No special.

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

No special.

Information to medics

Bring this safety data sheet or the label from this product.

SECTION 5: Firefighting measures

5.1. Extinguishing media

No special.

5.2. Special hazards arising from the substance or mixture

Fire will result in dense smoke. Exposure to combustion products may harm your health. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-extinguishing water to enter the sewage system and nearby surface waters.

5.3. Advice for firefighters

Fire fighters should wear appropriate personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No specific requirements.

6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc.

6.3. Methods and material for containment and cleaning up

Use sand, earth, vermiculite, diatomaceous earth to contain and collect non-combustible absorbent materials and place in container for disposal, according to local regulations.

Wherever possible cleaning should be performed with normal cleaning agents. Avoid use of solvents.

6.4. Reference to other sections

See section 13 "Disposal considerations" on handling of waste.

See section 8 "Exposure controls/personal protection" for protective measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Smoking, drinking and consumption of food is not allowed in the work area.

See section 8 "Exposure controls/personal protection" for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

No special conditions required.

Recommended storage material

Always store in containers of the same material as the original container.

Storage temperature

No specific requirements

Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No substances are listed in the national list of substances with an occupational exposure limit.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

Control is unnecessary if the product is used as intended.

General recommendations

Smoking, drinking and consumption of food is not allowed in the work area.

Exposure scenarios

There are no exposure scenarios implemented for this product.

Exposure limits

Occupational exposure limits have not been defined for the substances in this product.

Appropriate technical measures

Apply standard precautions during use of the product. Avoid inhalation of vapours.

Hygiene measures

Wash hands after use.

Measures to avoid environmental exposure

No specific requirements.

Individual protection measures, such as personal protective equipment

Generally

Use only CE marked protective equipment.

Respiratory Equipment

| Type | Class | Colour | Standards |
|--------------------------|-------|--------|-----------|
| No specific requirements | | | |

Skin protection

| Recommended | Type/Category | Standards |
|---------------------------|---------------|-----------|
| No specific requirements. | - | - |

Hand protection

| Material | Glove thickness (mm) | Breakthrough time (min.) | Standards |
|--------------------------|----------------------|--------------------------|-----------|
| No specific requirements | - | - | - |

Eye protection

| Type | Standards |
|---|-----------|
| Face shield alternatively safety glasses with side shields. | EN166 |



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Liquid

Colour

Clear

Odour / Odour threshold

No data available

pH

3.2 - 7.0

Density (g/cm³)

1.144 - 1.160

Kinematic viscosity

No data available

Particle characteristics

Does not apply to liquids.

Phase changes

Melting point/Freezing point (°C)

No data available

Softening point/range (waxes and pastes) (°C)

Does not apply to liquids.

Boiling point (°C)

No data available

Vapour pressure

No data available

Relative vapour density

No data available

Decomposition temperature (°C)

No data available

Data on fire and explosion hazards

Flash point (°C)

Testing not relevant or not possible due to nature of the product.

Ignition (°C)

Testing not relevant or not possible due to nature of the product.

Auto flammability (°C)

Testing not relevant or not possible due to nature of the product.

Lower and upper explosion limit (% v/v)

Testing not relevant or not possible due to nature of the product.

Solubility

Solubility in water

Soluble

n-octanol/water coefficient

No data available

Solubility in fat (g/L)

No data available

9.2. Other information

Evaporation rate (n-butylacetate = 100)

No data available

Other physical and chemical parameters

No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

The product is stable under the conditions, noted in section 7 "Handling and storage".

10.3. Possibility of hazardous reactions

No special.

10.4. Conditions to avoid

No special.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

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 sensitisation

Based on available data, the classification criteria are not met.

Skin sensitisation

Based on available data, the classification criteria are not met.

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.

11.2. Information on other hazards

Long term effects

No special.

Endocrine disrupting properties

No special.

Other information

No special.

SECTION 12: Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

12.6. Endocrine disrupting properties

No special.

12.7. Other adverse effects

No special.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product is not covered by regulations on dangerous waste.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

EWC code

Not applicable.

Specific labelling

Not applicable.

Contaminated packing

Packaging containing residues of the product must be disposed of similarly to the product.

SECTION 14: Transport information

| | 14.1 UN / ID | 14.2 UN proper shipping name | 14.3 Hazard class(es) | 14.4 PG* | 14.5 Env** | Other information |
|------|--------------|------------------------------|-----------------------|----------|------------|-------------------|
| ADR | - | - | - | - | - | - |
| IMDG | - | - | - | - | - | - |
| IATA | - | - | - | - | - | - |

* Packing group

** Environmental hazards

Additional information

Not dangerous goods according to ADR, IATA and IMDG.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

No data available.

SECTION 15: Regulatory information

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

Restrictions for application

Restricted to professional users.

Demands for specific education

No specific requirements.

SEVESO - Categories / dangerous substances

Not applicable.

Additional information

Not applicable.

Sources

Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP).

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

No

SECTION 16: Other information

Abbreviations and acronyms

ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road

ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

CAS = Chemical Abstracts Service

CE = Conformité Européenne

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

CSA = Chemical Safety Assessment

CSR = Chemical Safety Report

DMEL = Derived Minimal Effect Level

DNEL = Derived No Effect Level

EINECS = European Inventory of Existing Commercial chemical Substances

ES = Exposure Scenario

EUH statement = CLP-specific Hazard statement

EWC = European Waste Catalogue

GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IARC = International Agency for Research on Cancer (IARC)
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
OECD = Organisation for Economic Co-operation and Development
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
RRN = REACH Registration Number
SCL = A specific concentration limit
SVHC = Substances of Very High Concern
STOT-RE = Specific Target Organ Toxicity - Repeated Exposure
STOT-SE = Specific Target Organ Toxicity - Single Exposure
TWA = Time weighted average
UN = United Nations
UVBC = Unknown or variable composition, complex reaction products or of biological materials
VOC = Volatile Organic Compound
vPvB = Very Persistent and Very Bioaccumulative

Additional information

In accordance with Article 31 of REACH, a safety data sheet is not required for this product. This safety data sheet has been created on a voluntary basis to distribute relevant information as required under Article 32 of REACH.

The safety data sheet is validated by

Morten Givard / Sikma Consult / www.sikma.dk

Other

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue triangle.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

Country-language: DK-en