

Heparin sodium 25 ME

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 09/02/2015 Revision date: 24/02/2017

900146

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Heparin sodium 25 ME
Chemical name : Poly-β-D-glucuronil (D-L-iduronyl,D-L-iduronyl-2-O-solfato)1-4 D-N-sulphonyl-glucosamina-6(3)-O-(di)sulfate,sodium salt
CAS No : 9041-08-1
Product code : 900146
Synonyms : Heparin Sodium
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Industrial/Professional use spec : Industrial
For professional use only
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
Function or use category : Anti thrombotic , Anti-clotting agent

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

| Country | Organisation/Company | Address | Emergency number | Comment |
|----------------|--|---------------------------------|------------------|---------|
| United Kingdom | Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine | Avonley Road SE14 5ER London | 0870 243 2241 | |

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

| | |
|--|------|
| Acute toxicity (oral), Category 4 | H302 |
| Acute toxicity (inhalation:dust,mist) Category 4 | H332 |
| Sensitisation — Skin, category 1B | H317 |

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H302+H332 - Harmful if swallowed or if inhaled
H317 - May cause an allergic skin reaction

Precautionary statements (CLP) : P280 - Wear eye protection, face protection, protective gloves, protective clothing
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients**3.1. Substances**

Substance type : Pharmaceuticals

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|----------------------|--------------------|-----|--|
| Heparin sodium 25 ME | (CAS No) 9041-08-1 | 100 | Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Sens. 1B, H317 |

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). |
| First-aid measures after inhalation | : Assure fresh air breathing. Allow the victim to rest. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell. |
| First-aid measures after skin contact | : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. |
| First-aid measures after eye contact | : Obtain medical attention if pain, blinking or redness persists. Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. |
| First-aid measures after ingestion | : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER or doctor/physician if you feel unwell. |

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

| | |
|------------------------------------|--|
| Symptoms/injuries after inhalation | : Danger of serious damage to health by prolonged exposure through inhalation. Harmful if inhaled. |
| Symptoms/injuries after ingestion | : Swallowing a small quantity of this material will result in serious health hazard. |

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

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

| | |
|------------------------------|--|
| Suitable extinguishing media | : Foam. Dry powder. Carbon dioxide. Water spray. Sand. |
|------------------------------|--|

5.2. Special hazards arising from the substance or mixture

| | |
|--|--|
| Hazardous decomposition products in case of fire | : Thermal decomposition generates : Sulphur oxides. Carbon oxides (CO, CO ₂). Nitrogen oxides. Hazardous combustible gases and vapors. |
|--|--|

5.3. Advice for firefighters

| | |
|--------------------------------|---|
| Firefighting instructions | : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment. |
| Protection during firefighting | : Do not enter fire area without proper protective equipment, including respiratory protection. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|------------------|---|
| General measures | : Use special care to avoid static electric charges. Keep away from ignition sources. |
|------------------|---|

6.1.1. For non-emergency personnel

| | |
|----------------------|-----------------------------------|
| Emergency procedures | : Evacuate unnecessary personnel. |
|----------------------|-----------------------------------|

6.1.2. For emergency responders

| | |
|----------------------|--|
| Protective equipment | : Equip cleanup crew with proper protection. |
| Emergency procedures | : Ventilate area. |

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Additional hazards when processed : Avoid contact with skin and eyes. Avoid inhalation of the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from
: Keep container closed when not in use.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Personal protective equipment:**

Avoid all unnecessary exposure.

Hand protection:

| Type | Material | Permeation | Thickness (mm) | Standard |
|--------|----------------------|-------------------|----------------|----------|
| Gloves | Nitrile rubber (NBR) | 6 (> 480 minutes) | 0,11 | EN 374 |

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P2

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|------------------------------------|
| Physical state | : Solid |
| Appearance | : Powder. |
| Colour | : White. |
| Odour | : odourless. |
| Odour threshold | : No data available |
| pH | : 5.5 - 8 1 % Aqueous solution |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : No data available |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Auto-ignition temperature | : 350 °C (referred to saccharose) |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : Non flammable |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : Soluble in water. |
| Log Pow | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : Potential dust explosion hazard. |
| Oxidising properties | : No data available |
| Explosive limits | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Dust clouds can be explosive.

10.2. Chemical stability

Stable under normal conditions. Hygroscopic.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. Use special care to avoid static electric charges. Avoid dust clouds in combination with static electricity.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Oral: Harmful if swallowed. Inhalation:dust,mist: Harmful if inhaled.

| Heparin sodium 25 ME (9041-08-1) | |
|----------------------------------|------------------|
| LD50 oral rat | 1550 mg/kg |
| LD50 oral | 300 - 2000 mg/kg |

Skin corrosion/irritation : Not classified
pH: 5.5 - 8 1 % Aqueous solution

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
pH: 5.5 - 8 1 % Aqueous solution

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms : Harmful if swallowed. Harmful if inhaled.

SECTION 12: Ecological information**12.1. Toxicity**

Ecology - water : In case of fortuitous release and contact with water parts, the product gives rise to and increase of the COD,BOD values and heavy metals (Iron).

12.2. Persistence and degradability

| Heparin sodium 25 ME (9041-08-1) | |
|----------------------------------|------------------|
| Persistence and degradability | Not established. |

12.3. Bioaccumulative potential

| Heparin sodium 25 ME (9041-08-1) | |
|----------------------------------|------------------|
| Bioaccumulative potential | Not established. |

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Regional legislation (waste) : Disposal must be done according to official regulations.

Waste treatment methods : Remove to an authorized incinerator equipped with an afterburner and a flue gas scrubber.

Waste disposal recommendations : Avoid release to the environment. Remove to an authorized waste treatment plant.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

| ADR | IATA |
|---|------------------------------------|
| 14.1. UN number | |
| Not applicable | Not applicable |
| 14.2. UN proper shipping name | |
| Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | |
| Not applicable | Not applicable |
| Not applicable | Not applicable |
| 14.4. Packing group | |
| Not applicable | Not applicable |
| 14.5. Environmental hazards | |
| Dangerous for the environment : No | Dangerous for the environment : No |
| No supplementary information available | |

14.6. Special precautions for user**- Overland transport**

No data available

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Heparin sodium 25 ME is not on the REACH Candidate List

Heparin sodium 25 ME is not on the REACH Annex XIV List

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15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

| | | | |
|-----|--------------------------|----------|---|
| 1.4 | Emergency telephone | Modified | Added additional information |
| 2 | Classification (DSD/DPD) | Removed | Obsolete |
| 8.2 | Hand protection | Modified | Specified material, thickness, et cetera of gloves |
| 8.2 | Respiratory protection | Modified | Added additional information (type of clothing related to concentration levels) |

Abbreviations and acronyms:

| | |
|-------|---|
| SDS | Safety Data Sheet |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| IMDG | International Maritime Dangerous Goods |
| IATA | International Air Transport Association |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |

Data sources : 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:

| | |
|--|--|
| Acute Tox. 4 (Inhalation:dust,mist) | Acute toxicity (inhalation:dust,mist) Category 4 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4 |
| Skin Sens. 1B | Sensitisation — Skin, category 1B |
| H302 | Harmful if swallowed |
| H317 | May cause an allergic skin reaction |
| H332 | Harmful if inhaled |

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