

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 03/06/2025 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Leuprorelin
Chemical name : Leuprorelin acetate
CAS-No. : 74381-53-6
Product code : 201700517

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Endocrine disruptor for the environment, Category 2 EUH431
Endocrine disruptor for human health, Category 1 EUH380
Carcinogenicity, Category 2 H351
Reproductive toxicity, Category 1A H360Fd
Specific target organ toxicity – Single exposure, Category 2 H371
Specific target organ toxicity – Repeated exposure, Category 1 H372
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Suspected of causing cancer. May damage fertility. Suspected of damaging the unborn child. May cause damage to organs. Causes damage to organs through prolonged or repeated exposure.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) :

Danger

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

- Hazard statements (CLP) : EUH380 - May cause endocrine disruption in humans.
EUH431 - Suspected of causing endocrine disruption in the environment.
H351 - Suspected of causing cancer.
H360Fd - May damage fertility. Suspected of damaging the unborn child.
H371 - May cause damage to organs (respiratory system).
H372 - Causes damage to organs (central nervous system, cardiovascular system, endocrine system, skeleton, digestive system) through prolonged or repeated exposure.
- Precautionary statements (CLP) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P263 - Avoid contact during pregnancy and while nursing.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.
P314 - Get medical advice/attention if you feel unwell.
P391 - Collect spillage.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP) :



GHS08

2.3. Other hazards

The substance is included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

- Other information : Active substance (in pharmaceutical products).
Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---------------------|-------|--|
| Leuprorelin acetate substance identified as having endocrine disrupting properties | CAS-No.: 74381-53-6 | ≤ 100 | ED ENV 2, EUH431 ED HH 1, EUH380 Carc. 2, H351 Repr. 1A, H360Fd STOT SE 2, H371 STOT RE 1, H372 |

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| | |
|---------------------------------------|--|
| 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 | : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists. |
| First-aid measures after ingestion | : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention. |

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--------------------------------|---|
| Suitable extinguishing media | : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket. |
| Unsuitable extinguishing media | : Do not use a heavy water stream. |

5.2. Special hazards arising from the substance or mixture

| | |
|--|--|
| Hazardous decomposition products in case of fire | : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released. |
|--|--|

5.3. Advice for firefighters

| | |
|--------------------------------|--|
| Firefighting instructions | : Prevent fire fighting water from entering the environment. |
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|------------------|---|
| General measures | : Avoid contact with skin, eyes and clothing. |
|------------------|---|

For non-emergency personnel

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

For emergency responders

| | |
|----------------------|---|
| Protective equipment | : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |
|----------------------|---|

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

| | |
|-------------------------|---|
| For containment | : Absorb with an inert material and place in an appropriate waste disposal container. |
| Methods for cleaning up | : Clean contaminated surfaces with an excess of water. Clean with the help of detergents. |

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

| | |
|-----------------------------------|--|
| Additional hazards when processed | : Do not expose pregnant or breastfeeding women. |
|-----------------------------------|--|

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| | |
|-------------------------------|--|
| Precautions for safe handling | : Avoid all unnecessary exposure. Ensure good ventilation of the work station. |
| Hygiene measures | : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work. |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|---------------------|---|
| Storage conditions | : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight. |
| Packaging materials | : Keep in original containers. |

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

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---------------------------|------------------------|
| Physical state | : Solid |
| Colour | : white. almost white. |
| Appearance | : Powder. |
| Molecular mass | : 1269.4 g/mol |
| Odour | : Not available |
| Odour threshold | : Not available |
| Melting point | : 170 °C |
| Freezing point | : Not available |
| Boiling point | : Not available |
| Flammability | : Not available |
| Lower explosion limit | : Not applicable |
| Upper explosion limit | : Not applicable |
| Flash point | : Not applicable |
| Auto-ignition temperature | : Not applicable |
| Decomposition temperature | : Not available |
| pH | : Not available |

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| | |
|---|---------------------|
| pH solution | : Not available |
| Viscosity, kinematic | : Not applicable |
| Solubility | : Water: > 1000 g/l |
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Vapour pressure | : Not available |
| Vapour pressure at 50°C | : Not available |
| Density | : Not available |
| Relative density | : Not available |
| Relative vapour density at 20°C | : Not applicable |
| Particle size | : Not available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

| | |
|-----------------------------|---|
| Acute toxicity (oral) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (dermal) | : Not classified (Lack of data) |
| Acute toxicity (inhalation) | : Not classified (Lack of data) |

Leuprorelin acetate (74381-53-6)

| | |
|---------------|-----------------------------------|
| LD50 oral rat | > 5000 mg/kg (RTECS No OH6390000) |
|---------------|-----------------------------------|

| | |
|-----------------------------------|---|
| Skin corrosion/irritation | : Not classified (Lack of data) |
| Serious eye damage/irritation | : Not classified (Lack of data) |
| Respiratory or skin sensitisation | : Not classified (Lack of data) |
| Germ cell mutagenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Carcinogenicity | : Suspected of causing cancer. |
| Reproductive toxicity | : May damage fertility. Suspected of damaging the unborn child. |
| STOT-single exposure | : May cause damage to organs (respiratory system). |
| STOT-repeated exposure | : Causes damage to organs (central nervous system, cardiovascular system, endocrine system, skeleton, digestive system) through prolonged or repeated exposure. |
| Aspiration hazard | : Not classified (Lack of data) |

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

11.2. Information on other hazards

Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Lack of data)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Lack of data)

12.2. Persistence and degradability

Leuprorelin acetate (74381-53-6)

| | |
|-------------------------------|--------------------|
| Persistence and degradability | Rapidly degradable |
|-------------------------------|--------------------|

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system.

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

| ADR | IMDG | IATA |
|---|---------------|---------------|
| 14.1. UN number or ID number | | |
| Not regulated for transport | | |
| 14.2. UN proper shipping name | | |
| Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | |
| Not regulated | Not regulated | Not regulated |

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| ADR | IMDG | IATA |
|--|---------------|---------------|
| 14.4. Packing group | | |
| Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards | | |
| Not regulated | Not regulated | Not regulated |
| No supplementary information available | | |

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

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-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 16: Other information

| Indication of changes | | |
|-----------------------|--|-----------------|
| Section | Changed item | Comments |
| | Adverse health effects caused by endocrine disrupting properties | Added |
| | Supersedes version of | Added |
| | Revision date | Added |
| 1.1 | EC-No. | Added |
| 1.1 | CAS-No. | Added |
| 1.1 | Name | Modified |
| 1.2 | Restrictions on use | Added |
| 1.2 | Use of the substance/mixture | Added |
| 1.2 | Function or use category | Added |
| 2.1 | Adverse physicochemical, human health and environmental effects | Added |
| 2.1 | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Added |
| 2.2 | Hazard statements (CLP) | Added |
| 2.2 | Precautionary statements (CLP) | Added |
| 2.2 | Signal word (CLP) | Added |
| 2.2 | Hazard pictograms (CLP) | Added |
| 2.3 | Other information | Added |
| 4.1 | First-aid measures general | Added |
| 4.1 | First-aid measures after skin contact | Added |
| 4.1 | First-aid measures after inhalation | Added |
| 4.1 | First-aid measures after ingestion | Added |
| 4.1 | First-aid measures after eye contact | Added |
| 5.1 | Unsuitable extinguishing media | Added |
| 5.1 | Suitable extinguishing media | Added |
| 5.2 | Hazardous decomposition products in case of fire | Added |
| 5.3 | Protection during firefighting | Added |
| 5.3 | Firefighting instructions | Added |
| 6.1 | Protective equipment | Added |
| 6.1 | Emergency procedures | Added |
| 6.1 | General measures | Added |
| 6.2 | Environmental precautions | Added |
| 6.3 | For containment | Added |
| 6.3 | Methods for cleaning up | Added |
| 6.4 | Reference to other sections (8, 13) | Added |
| 7.1 | Additional hazards when processed | Added |

Leuprorelin

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| Indication of changes | | |
|-----------------------|--|-----------------|
| Section | Changed item | Comments |
| 7.1 | Precautions for safe handling | Added |
| 7.1 | Hygiene measures | Added |
| 7.2 | Storage conditions | Added |
| 7.2 | Packaging materials | Added |
| 8.2 | Respiratory protection | Added |
| 8.2 | Hand protection | Added |
| 8.2 | Eye protection | Added |
| 8.2 | Appropriate engineering controls | Added |
| 8.2 | Skin and body protection | Added |
| 9 | Molecular mass | Added |
| 9 | Colour | Added |
| 9 | Appearance | Modified |
| 9 | Solubility in water | Added |
| 11.1 | LD50 oral rat | Modified |
| 12.6 | Adverse effects on the environment caused by endocrine disrupting properties | Added |

| Full text of H- and EUH-statements: | |
|-------------------------------------|---|
| Carc. 2 | Carcinogenicity, Category 2 |
| ED ENV 2 | Endocrine disruptor for the environment, Category 2 |
| ED HH 1 | Endocrine disruptor for human health, Category 1 |
| EUH380 | May cause endocrine disruption in humans. |
| EUH431 | Suspected of causing endocrine disruption in the environment. |
| H351 | Suspected of causing cancer. |
| H360Fd | May damage fertility. Suspected of damaging the unborn child. |
| H371 | May cause damage to organs (respiratory system). |
| H372 | Causes damage to organs (central nervous system, cardiovascular system, endocrine system, skeleton, digestive system) through prolonged or repeated exposure. |
| Repr. 1A | Reproductive toxicity, Category 1A |
| STOT RE 1 | Specific target organ toxicity – Repeated exposure, Category 1 |
| STOT SE 2 | Specific target organ toxicity – Single exposure, Category 2 |

Safety Data Sheet (SDS), EU

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