

Material Safety Data Sheet

Sedastart 1 mg/ml solution for injection

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Sedastart 1 mg/ml solution for injection
Product code(s): XVD 200 (10 ml vials)

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

Relevant identified uses: Veterinary medicinal product
Uses advised against: Not for human use. Refer to the product information leaflet
Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited
Address: 10 Great Northway
York Business Park
Nether Poppleton
York
YO26 6RB
United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms: Not applicable
Signal word: Not applicable
Hazard statements: Not applicable
Precautionary statements: Not applicable
Supplemental information: Sedative/Analgesic

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC) None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

| <i>Substance name in the mixture</i> | <i>CAS No</i> | <i>Quantity</i> |
|--------------------------------------|---------------|-----------------|
| Medetomidine HCl | [106807-72-1] | 0.1% |
| Methyl parahydroxybenzoate | [99-76-3] | 0.1% |
| Propyl parahydroxybenzoate | [94-13-3] | 0.02% |
| Sodium chloride | [7647-14-5] | Proprietary |
| Water | [7732-18-5] | Proprietary |

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|-------------------|---|
| Eyes: | In the case of accidental contact of the product with eyes, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician |
| Skin: | Avoid skin contact. Wash the exposed skin immediately after exposure with large amounts of water. Remove contaminated clothes that are in direct contact with skin |
| Ingestion: | In the case of accidental oral intake, seek medical advice immediately and show the package insert to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur |
| Injection: | In the case of accidental self injection, seek medical advice immediately and show the package insert to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur |

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

4.3 Indication of any immediate medical attention and special treatment needed

See patient package insert in shipping carton for complete information.
No specific measures identified. Seek medical advice if required

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

| | |
|--|---|
| Suitable extinguishing media: | Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings |
| Unsuitable extinguishing media: | None known |

5.2 Special hazards arising from the substance or mixture

| | |
|--|--|
| Specific hazards during firefighting: | Not flammable or combustible |
| Hazardous combustion products: | When heated to decomposition, it may emit toxic fumes of HCl |

5.3 Advice for fire-fighters

| | |
|---|--|
| Special protective equipment for firefighters: | Wear self-containing breathing apparatus and protective clothing |
| Further information: | Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations |

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Refer to protective measures listed in sections 7 and 8

Advice for emergency responders: If specialised clothing is required to deal with the spillage, take note of any information in section 8 on suitable and unsuitable materials

6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Small spills: Wear recommended personal protective equipment (see section 8- Exposure controls/personal Protection). Use absorbent towels or brooms to clean up spill. Wipe surface area clean with soap and water

Large spills: Dike spilled material or otherwise contain material to ensure runoff does not reach a waterway

6.4 Reference to other sections

See Section 1 for emergency contact information

See section 8 for personal protection

See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product

Hygiene measures: None identified

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep out of reach of children. Keep in the original packaging. Keep container tightly closed

Storage temperature: Store at ambient temperature. Do not freeze

Further information on storage conditions: Keep in a dry, cool and well-ventilated place

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, none of the constituents have known exposure limits

8.2 Exposure controls

Engineering measures: Good general ventilation should be sufficient to control worker exposure to airborne contaminants

Individual protection measures:

Hygiene measures: No specific measures identified

| | |
|---|---|
| Eye/face protection: | Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent) |
| Skin/body protection: | Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent) |
| Hand protection: | Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent) |
| Respiratory protection: | Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent) |
| Environmental exposure controls: | Consider the provision of containment around storage vessels |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| | |
|-----------------------------------|---|
| Appearance | Liquid |
| Colour: | Clear, colourless |
| Odour: | None |
| Odour threshold: | No data available |
| pH: | No data available |
| Density: | No data available |
| Melting point: | No data available |
| Boiling point: | No data available |
| Flash point: | No data available |
| Evaporation rate: | No data available |
| Flammability: | No data available |
| Water solubility: | No data available |
| Partition coefficient: | No data available |
| Auto-ignition temperature: | No data available |
| Thermal decomposition: | No data available |
| Viscosity: | No data available |
| Vapour pressure: | No data available |
| Vapour density: | No data available |
| Explosive properties: | No data available |
| Oxidizing properties: | The substance or mixture is not classified as oxidizing |

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

None Known

10.6 Hazardous decomposition products

Decomposition products may include the following materials: Fumes of HCl

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

| | |
|---------------------------------------|--|
| Acute toxicity: | No data available |
| Chronic toxicity: | No data available |
| Skin irritation/sensitization: | No data available |
| Reproductive toxicity: | No data available |
| Carcinogenicity: | Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data |
| Mutagenicity: | 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

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15: REGULATORY INFORMATION

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

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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