

Sedator 1.0 mg/ml solution for injection

GHS Safety Data Sheet - (Conforms to Regulation (EC) No 1907/2006, Article 31.)
Issue Date: 5-Mar-2012
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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Sedator 1.0 mg/ml solution for injection

PRODUCT USE

Used according to manufacturer's directions.

SUPPLIER

Company: Eurovet Animal Health B.V.
Address: Handelsweg 25
Bladel, 5530 AE Netherlands
Telephone: +31 497 544 300
Fax: +31 497 544 302

Section 2 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Not hazardous

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Contains per ml:	CAS RN
1.00 mg medetomidine hydrochloride	86347-15-1

Section 4 - FIRST AID MEASURES

SWALLOWED

- 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.

EYE

- If this product comes in contact with the eyes,
- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

Avoid skin or mucosal contact.

Wash the exposed skin immediately after exposure with large amounts of water.

Remove contaminated clothes that are in direct contact with skin.

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.

- If there is evidence of severe skin irritation or skin burns:
- Flush skin under running water for 15 minutes.
- Avoiding contamination of the hands, massage calcium gluconate gel into affected areas, pay particular attention to creases in skin.
- Contact the Poisons Information Centre.

INHALED

- If fumes, aerosols or combustion products are inhaled remove from contaminated area.

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NOTES TO PHYSICIAN

Medetomidine is an alpha2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves in the event of a fire.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.

FIRE/EXPLOSION HAZARD

- Non combustible.
- Not considered a significant fire risk, however containers may burn.

FIRE INCOMPATIBILITY

- None known.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up all spills immediately.
- Avoid breathing vapours and contact with skin and eyes.
- Control personal contact with the substance, by using protective equipment.
- Contain and absorb spill with sand, earth, inert material or vermiculite.

MAJOR SPILLS

Minor hazard.

- Clear area of personnel.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact with the substance, by using protective equipment as required.
- Prevent spillage from entering drains or water ways.

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Limit all unnecessary personal contact.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the case of accidental oral intake or 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.
Avoid skin, eye or mucosal contact.
Wash the exposed skin immediately after exposure with large amounts of water.
Remove contaminated clothes that are in direct contact with skin.

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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.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

SUITABLE CONTAINER

Glass vials of 5, 10 or 20 ml, rubber stopper and aluminium cap; 1 vial in cardboard box.

STORAGE INCOMPATIBILITY

None known.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Do not freeze.
- Store away from foodstuff containers.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- medetomidine hydrochloride:

CAS:86347- 15- 1

PERSONAL PROTECTION

EYE

- Safety glasses with side shields
- Chemical goggles.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent].

HANDS/FEET

- Wear general protective gloves, eg. light weight rubber gloves.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Change gloves frequently and when contaminated, punctured or torn.

OTHER

- No special equipment needed when handling small quantities. OTHERWISE:
- Overalls.
- Barrier cream.
- Eyewash unit.

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Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Liquid; mixes with water.

PHYSICAL PROPERTIES

Liquid.

Mixes with water.

State	Liquid
Solubility in water (g/L)	Miscible
pH (as supplied)	4.8

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Product is considered stable.
 - Hazardous polymerisation will not occur.
- For incompatible materials - refer to Section 7 - Handling and Storage.*

Section 11 - TOXICOLOGICAL INFORMATION

Health hazard summary table:

Acute toxicity	Not applicable
Skin corrosion/irritation	Not applicable
Serious eye damage/irritation	Not applicable
Respiratory or skin sensitization	Not applicable
Germ cell mutagenicity	Not applicable
Carcinogenicity	Not applicable
Reproductive toxicity	Not applicable
STOT- single exposure	Not applicable
STOT- repeated exposure	Not applicable
Aspiration hazard	Not applicable

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.

EYE

- Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

INHALED

- The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
- Not normally a hazard due to non-volatile nature of product.

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CHRONIC HEALTH EFFECTS

Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.

TOXICITY AND IRRITATION

- Not available. Refer to individual constituents.

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
medetomidine hydrochloride	No data Available	No Data Available	No data Available	No data Available

Section 13 - DISPOSAL CONSIDERATIONS

- Consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or incineration in a licenced apparatus (after admixture with suitable combustible material).
- Observe all label safeguards until containers are cleaned and destroyed.

- According to the European Waste Catalogue, Waste Codes are not product specific but application specific. Waste Codes should be assigned by the User based on the application in which the product is used.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:

None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: ADR, IATA, IMDG

Section 15 - REGULATORY INFORMATION

RISK

- None under normal operating conditions.

REGULATIONS

This safety data sheet is in compliance with the following EU legislation and its adaptations – as far as applicable - : 67/548/EEC, 1999/45/EC, 98/24/EC, 92/85/EEC, 94/33/EC, 91/689/EEC, 1999/13/EC, Regulation (EU) No 453/2010, Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008, and their amendments.

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Section 16 - OTHER INFORMATION

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

■ For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 16 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices.

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