

Complying to Regulation (EC) 1907/2006

## Material Safety Data Sheet

### Sedadex 0.5 mg/ml Solution for Injection

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

##### 1.1 Product identification

Product name(s): Sedadex 0.5 mg/ml Solution for Injection  
Product code(s): XVD140

##### 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: Not applicable

##### 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>% [weight]</i>
Dexmedetomidine HCL	[113775-47-6]	0.05%
Methyl parahydroxybenzoate	[99-76-3]	0.2%
Propyl parahydroxybenzoate	[94-13-3]	0.02%
Sodium Chloride	[7647-14-5]	Proprietary
Water for injections	[7732-18-5]	Proprietary

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Eyes:</b>	In case of eye contact Rinse abundantly with fresh water
<b>Skin:</b>	In case of skin contact wash the exposed skin immediately after exposure with large amounts of water. Remove contaminated clothes that are in direct contact with skin. Rinse with water
<b>Ingestion:</b>	Rinse mouth. Get medical attention if symptoms occur. Do not drive as sedation and changes in blood pressure may occur
<b>Inhalation:</b>	This route of exposure is unlikely. Get medical attention if symptoms occur
<b>Injection:</b>	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

No specific measures identified. Seek medical advice if required

## SECTION 5: FIRE- FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media:</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
<b>Unsuitable extinguishing media:</b>	None known

### 5.2 Special hazards arising from the substance or mixture

<b>Specific hazards during firefighting:</b>	Not flammable or combustible
<b>Hazardous combustion products:</b>	Decomposition products may include the following materials: Carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> )

### 5.3 Advice for fire-fighters

<b>Special protective equipment for firefighters:</b>	Use personal protective equipment. Hazardous Combustion Products: When heated to decomposition, it may emit toxic fumes of HCl.
<b>Further information:</b>	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

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

**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

### 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:** Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls

**Hygiene measures:** Wash hands

### 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

**Storage temperature:** Store between 5 and 25 °C

**Further information on storage conditions:** Protect from direct incidence of light

### 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, the other constituents have no known exposure limits

<i>Substance name in the mixture</i>	<i>Type</i>	<i>Value</i>
Dexmedetomidine HCL	OEB	<1µg/m <sup>3</sup>

## 8.2 Exposure controls

<b>Engineering measures:</b>	Good general ventilation should be sufficient to control worker exposure to airborne contaminants
<b>Individual protection measures:</b>	
<b>Hygiene measures:</b>	No specific measures identified
<b>Eye/face protection:</b>	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)
<b>Skin/body protection:</b>	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)
<b>Hand protection:</b>	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)
<b>Respiratory protection:</b>	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)
<b>Environmental exposure controls:</b>	Consider the provision of containment around storage vessels

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Liquid
<b>Colour:</b>	Clear colourless
<b>Odour:</b>	None
<b>Odour threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Density:</b>	No data available
<b>Melting point:</b>	No data available
<b>Boiling point:</b>	No data available
<b>Flash point:</b>	No data available
<b>Evaporation rate:</b>	No data available
<b>Flammability:</b>	No data available
<b>Water solubility:</b>	Soluble
<b>Partition coefficient:</b>	No data available
<b>Auto-ignition temperature:</b>	No data available
<b>Thermal decomposition:</b>	No data available
<b>Viscosity:</b>	No data available
<b>Vapour pressure:</b>	No data available
<b>Vapour density:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	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: Carbon oxides nitrogen oxides

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

<b>Acute toxicity:</b>	Sodium chloride LD <sub>50</sub> 3 g/kg (Rat, oral)
<b>Chronic toxicity:</b>	No data available
<b>Skin irritation/sensitization:</b>	Sodium chloride – Eye irritation Rabbit - Mild
<b>Reproductive toxicity:</b>	Dexmedetomidine HCl NOAEL 20 µg/kg (Rat, SC) – Fetal development Dexmedetomidine HCl NOAEL 2 µg/kg (Rat, SC) – Postnatal development Dexmedetomidine HCl NOAEL 96 µg/kg (Rabbit, IV) – Not teratogenic Dexmedetomidine HCl NOAEL 54 µg/kg (Rat, SC) – Fertility
<b>Carcinogenicity:</b>	No indication of human carcinogenicity
<b>Mutagenicity:</b>	Dexmedetomidine HCl – <i>In vitro</i> mammalian cell – Non mutagenic

## 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 as dangerous goods

## **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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