SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Sedadex 0.5 mg/ml solution for injection
Synonyms:	None
Proper Shipping name:	Not applicable
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Analgesic/sedative veterinary medicinal product.
Uses advised against:	**Not for human use.**
1.3 Details of the supplier of the substance or mixture	
Registered company name (EU):	Le Vet Beheer B.V.
Address:	Wilgenweg 7 3421 TV Oudewater The Netherlands
Telephone:	+31 (0)348 565858
Fax:	+31 (0)348 565454
Website:	www.dechra.com
Email:	Not available
Distributor name (Canada):	Dechra Veterinary Products
Address:	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3, Canada
Telephone:	+1 (855) 332-9334
Website:	www.dechra.ca
Email:	Not Available
1.4 Emergency Telephone Numbers	
Dechra (EU):	+31 (0)348 565858
Dechra (CA):	+1 (855) 332-9334

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture **REACH regulation no. 1907/2006 and 453/2010**	
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)[1]:	Not applicable
2.2 Label Elements	
Hazard Pictogram:	Not applicable
Signal Word:	Not available
Hazard statement(s):	
	Not applicable
Supplementary Statement(s) EU:	
	Not applicable
Precautionary Statement(s) Prevention:	
	Not applicable
Precautionary Statement(s) Response:	
	Not applicable
Precautionary Statement(s) Storage:	
	Not applicable
Precautionary Statement(s) Disposal:	
	P501 Dispose of contents/ container in accordance with local regulations

2.3 Other Hazard Information

Short Term: May be harmful if swallowed.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

No substances fulfill the criteria set forth in annex II section A of the REACH regulation (EC) no. 1907/2006

3.2 Mixtures

CAS No	Name	Quantity
113775-47-6	dexmedetomidine hydrochloride	0.5 mg/ml
99-76-3	Methyl parahydroxybenzoate	2.0 mg/ml
94-13-3	Propyl parahydroxybenzoate	0.2 mg/ml
7647-14-5	Sodium chloride	Classified
	Water for injections	
Legend:	*1. Classified by Chemwatch*	

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off immediately with plenty of water. Seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental spillage on the skin should be washed off with plenty of soap and water. Remove contaminated clothes that are in direct contact with skin. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
Ingestion:	If swallowed, do not induce vomiting. Seek medical advice immediately and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered.
Self-injection:	Care should be taken to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician, but DO NOT DRIVE as sedation and change in blood pressure may occur. Symptomatic treatment may be required.

4.2 Most important symptoms and effects, both acute and delayed	
Eye contact:	May cause eye irritation.
Skin contact:	May cause skin irritation.
Ingestion:	May cause discomfort if ingested in large quantities
Self-injection:	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.
See Section 11 for more detailed information	
4.3 Indication of immediate medical attention and special treatment needed None	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Select extinguishing media suitable for surrounding area .
Unsuitable:	There is no restriction on the type of extinguisher which may be used.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses DO NOT approach containers suspected to be hot. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn. Irritating and highly toxic gases may be generated from thermal decomposition or combustion.

SECTION 6: ACCIDENTAL RELEASE MEASURES
6.1 Personal precautions, protective equipment and emergency procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (See section 8). Minimize exposure.
6.2 Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3 Methods and material for containment and cleaning up	
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. Place in a suitable, labelled container for waste disposal.
Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent, by any means available, spillage from entering drains or water course.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling	
Safe Handling:	Wear suitable protection gloves and clothing when handling the product. When handling, **DO NOT** eat, drink or smoke. Always wash hands with water after handling. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Special caution should be observed by pregnant women as accidental self-injection may cause uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children.

7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	10 ml clear type II glass vials
Storage incompatibility:	Not available.

7.3 Specific end uses
Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

DERIVED NO EFFECT LEVEL – DNEL (EU)

Not Available

PREDICTED NO EFFECT LEVEL – PNEC (EU)

Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not available	Not available	Not available	Not available	Not available	Not available	Not available

EMERGENCY LIMITS (EU):

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
No data available	Not available	Not available	Not available	Not available

Ingredient	Original IDLH	Revised IDLH
No data available	Not available	Not available

8.2 Exposure controls

Appropriate engineering controls:	General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.
Personal protection:	
Eye and face protection:	Wear safety glasses or goggles if eye contact is possible.
Skin protection:	Disposable garments if direct skin contact is anticipated.
Hands/ feet protection:	Disposable latex gloves recommended
Body protection:	Wear appropriate clothing
Other protection:	Wear appropriate clothing
Thermal hazards:	Not applicable
Respiratory protection:	With satisfactory ventilation, respiratory protection is usually not required.

8.3 Environmental exposure controls

See Section 12

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Clear Solution for injection
Container:	10 ml clear type II glass vials
Physical state:	Liquid
Odour:	Odourless
Melting point / freezing point (degrees C):	Not available
Initial boiling point and boiling range:	Not applicable
Flash Point:	Not applicable
Evaporation rate :	Not applicable
Flammability:	Not available
Upper/lower flammability or explosive limits:	Not available
Vapour pressure:	Not applicable
Specific Gravity:	Not available
Solubility in water and solvents (mg/l):	Not applicable
Auto ignition temperature (degrees C):	Not available
Decomposition temperature (degrees C):	Not available
Viscosity: (degrees C):	Not available
Explosive properties:	Not available
Oxidising properties:	Not available
Partition Coefficient:	Not available
Taste:	Not applicable
Surface tension:	Not available
Volatile component:	Not available
Chemical group:	Dexmedetomidine HCl
pH:	Not available
VOC g/L:	Not applicable

9.2 Other information

Not Available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:	No data available
10.2 Chemical stability:	Stable under normal conditions of use.
10.3 Possibility of hazardous reactions:	No data available
10.4 Conditions to avoid:	Do not freeze
10.5 Incompatible materials:	No polymerization should occur
10.6 Hazardous decomposition:	No polymerization should occur

SECTION 11: TOXICOLOGICAL INFORMATION	
Inhalation:	The material is not thought to produce adverse health effects or irritation of the respiratory tract. Not normally a hazard due to non-volatile nature of product
Ingestion:	In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet and other product literature to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Skin contact:	May cause skin irritation
Eye contact:	May cause eye irritation
Chronic:	Overexposure: are described in the package insert.

Sedadex 0.5 mg/ml solution for injection	**Toxicity**	**Irritation**
	Not available	Not available

Skin corrosion/irritation:
No available
Serious eye damage/irritation:
No available
Respiratory or skin sensitization:
Not available
Germ cell mutagenicity:
No available
Carcinogenicity:
No available
Reproductive toxicity:
No available
STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

	Endpoint	Test duration (hr)	Species	Value	Source
Sedadex 0.5 mg/ml solution for injection	Not available	Not available	Not available	Not available	Not available

Environmental properties have not been investigated. Releases to the environment should be avoided.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
No data available	No data available	No data available

12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
No data available	No data available

12.4 Mobility in Soil

Ingredient	Mobility
No data available	No data available

12.5 Results of PBT and vPvB assessment

Not Applicable

12.6 Other adverse effects

Not Available

SECTION 13: DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
Product / packaging disposal:	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements. Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority. Disposal of this product is controlled by the Misuse of Drugs Regulations 2001.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION	
Labels required: None	
Marine pollutant:	NO
Hazchem:	Not applicable
No data available	
Land transport (EU: ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	

SECTION 15: REGULATORY INFORMATION

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

5.2 Chemical Safety Assessment

Ingredient	CAS number	Index Number	ECHA Dossier
All ingredients	No data available	Not available	Not available

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008 and their amendments.

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
No data available	No data available	No data available	No data available

Harmonisation Code 1 = the most prevalent classification.
Harmonisation Code 2 = The most severe classification

SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

Definitions and abbreviations
PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
IDLH: Immediately Dangerous to Life or Health Concentrations

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