

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Sedator® (1.0 mg/ml, solution for injection for cats and dogs).
Synonyms:	Not Available
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	<p><i>Dogs:</i> for restraint, sedation and analgesia associated with clinical examinations and procedures, minor surgery, pre-anaesthesia and as a premedication before thiopentone-halothane general anaesthesia and as a premedicant before general anaesthesia with propofol. In combination with butorphanol for sedation, analgesia and as a premedicant to thiopentone anaesthesia.</p> <p><i>Cats:</i> for restraint and sedation. In combination with ketamine for induction of general anaesthesia prior to surgical procedures in the cat. In combination with butorphanol for sedation and analgesia, and combined with both butorphanol and ketamine for general anaesthesia. As a premedication before alphaxalone/alphadolone for general anaesthesia.</p>
Uses advised against:	<p>Do not use in conjunction with sympathomimetic amines. Care should be taken with the use of medetomidine in animals with cardiovascular disease or in poor general health.</p> <p>Before using any combinations consult the contraindications and warnings that appear on the other products' data sheet.</p> <p>Medetomidine should not be used with thiopentone or propofol in animals with cardiac or respiratory disease.</p> <p>Pregnant women should take care when handling the product.</p>
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Ltd
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
Telephone:	+44 (0) 1756 791311



Fax:	+44 (0) 1756 798604
Email:	Not available
1.4 Emergency Telephone Numbers	
	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
DSD Classification (EU):	Not Available
DPD Classification (EU)¹:	Not Available
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	Not Available
2.2 Label Elements	
Signal Word:	NOT APPLICABLE
Hazard Statement(s)	
Not Applicable	
Additional Statement(s)	
EUH210	Safety data sheet available on request.
Precautionary Statement(s) Prevention:	
Not Applicable	
Precautionary Statement(s) Response:	
Not Applicable	
Precautionary Statement(s) Storage:	
Not Applicable	
Precautionary Statement(s) Disposal:	
Not Applicable	
2.3 Other Hazard Information	
REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.	

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 86347-15-1 2. Not Available 3. Not Available 4. Not Available	0.1%	Medetomidine hydrochloride	Acute Toxicity (Oral) Category 3, Reproductive Toxicity Category 2; H301, H361 ¹
N/a	Proprietary	Other ingredients determined not to be hazardous	N/a
Legend: 1. Classified by Chemwatch			

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	In case of accidental contact of the product with the eyes rinse abundantly with fresh water. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Skin contact:	In case of accidental contact of the product with the skin rinse abundantly with fresh water. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Inhalation:	In case of dust inhalation or breathing fumes released from heated material, remove person to fresh air.
Ingestion:	In the case of accidental oral intake, seek medical advice immediately and show the package leaflet to the doctor, but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Self-injection:	In the case of accidental self-injection, seek medical advice immediately and show the package leaflet to the doctor, but DO NOT DRIVE as sedation and changes in blood pressure may occur. 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.
4.2 Most important symptoms and effects, both acute and delayed	
See Section 11	
4.3 Indication of immediate medical attention and special treatment needed	
<p>ADVICE TO DOCTORS: 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.</p> <p>Atipamezole is useful as an antidote in animals. It gives a full recovery within 15 minutes after injection. No human authorisation exists for this indication. However, in the case of life threatening symptoms, use of atipamezole should be considered as a good tolerance has been demonstrated in human patients.</p>	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Select extinguishing media suitable for surrounding area; water, dry chemical, carbon dioxide or foam as appropriate.
Unsuitable:	None.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Cool containers with water spray. Wear full breathing apparatus and self-contained breathing apparatus.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn.

SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8.	
6.2 Environmental Precautions	
Do not allow product to reach sewage system or any water course.	

Inform respective authorities in case of seepage into water course or sewage system.
 Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Minor Spills:	No special requirements for spills from a single vial.
Major Spills:	Clean up all spills immediately. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. Control personal contact with the substance, by using protective equipment. Use absorbent towels or sand to clean up spills. Collect absorbed materials into a plastic container and treat as chemical waste. Avoid breathing vapours and contact with skin and eyes.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling


Safe Handling:	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. Wear suitable protection gloves and clothing when handling the product. Wash hands after use. When handling, DO NOT eat, drink or smoke. 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:	Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the container: 28 days. Keep vial in carton.
Storage incompatibility:	Medetomidine must not be mixed with other products with the exception of Vetalar and Torbugesic injection.

7.3 Specific end uses

Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION				
8.1 Control parameters				
DERIVED NO EFFECT LEVEL - DNEL				
Not Available				
PREDICTED NO EFFECT LEVEL - PNEC				
Not Available				
OCCUPATIONAL EXPOSURE LIMITS (OEL)				
INGREDIENT DATA:				
Not Available				
EMERGENCY LIMITS:				
Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Not Available				
Ingredient	Original IDLH		Revised IDLH	
Not Available				
8.2 Exposure controls				
Appropriate engineering controls:	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.			
Personal protection:				
Eye and face protection:	Safety glasses with side shields / chemical goggles			
Skin protection:	See hand protection below			
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves			
Body protection:	Wear appropriate clothing			
Other protection:	No special equipment needed when handling small quantities			
Thermal hazards:	Not applicable			
Respiratory protection:	Not applicable			
8.3 Environmental exposure controls				
See Section 12				

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Sedator®: clear and colourless solution
Container: White, polypropylene container with polyethylene, child resistant closure (100s)
 White, polypropylene container with polyethylene, tamper-evident, push-fit closure (500s)
Physical state: Sedator®: tablet
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Medetomidine HCl melting point: 170°C
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Solubility in water and solvents (mg/l): Not available
Vapour density: Not available
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
Molecular weight: Medetomidine HCl: 236.7
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information

Not Available

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is considered stable.
10.3 Possibility of hazardous reactions:	Stable under normal temperatures and conditions. Reacts explosively with bromine trifluoride.
10.4 Conditions to avoid:	Avoid contact with strong acids, strong oxidants and heavy metal salts.
10.5 Incompatible materials:	See section 7.

10.6 Hazardous decomposition:	See Section 5.
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SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	Due to physical form of this product, inhalation exposure is unlikely.	
Ingestion:	Can be toxic if swallowed. Sedation and changes in blood pressure may occur.	
Skin contact:	Minimal irritation potential (guinea pig test). However, irritation, sensitisation, contact dermatitis and systemic effects cannot be excluded after skin contact.	
Eye contact:	Minimal irritation potential (rabbit eye test). However, product is slightly acidic (pH = 5). Some absorption may be possible via the mucous membranes.	
Self-injection:	Sedation and changes in blood pressure may occur. Toxic symptoms like drowsiness may already occur following injection of very small amounts of medetomidine. See below for other effects.	
Chronic:	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.	
Sedator®:	Acute toxicity	Irritation
	Not Available	Not Available
Medetomidine hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 31 mg/kg ¹	Not Available

1. Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances*

Skin corrosion/ irritation:
May cause skin irritation in some people.
Serious eye damage/ irritation:
May cause irritation in some people.
Respiratory or skin sensitization:
May cause skin sensitisation in some people.
Germ cell mutagenicity:



SECTION 11: TOXICOLOGICAL INFORMATION
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Medetomidine has not been found to produce any mutagenic potential.

Carcinogenicity:

Medetomidine has not been found to produce any carcinogenic potential.
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Reproductive toxicity:

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.

STOT – single exposure:

Not available

STOT–repeated exposure:

Not available

Aspiration hazard:

Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not Available

12.2 Persistence and degradability

Not Available

12.3 Bioaccumulative potential

Not Available

12.4 Mobility in Soil

Not Available

12.5 Results of PBT and vPvB assessment
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Not Available

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. Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) 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

Land transport (ADR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	



14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Air transport (ICAO-IATA / DGR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a



14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Inland waterways transport (ADN):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
14.6 Special precautions for user	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in	N/a	

bulk according to Annex II of MARPOL73/78 and the IBC Code	
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SECTION 15: REGULATORY INFORMATION

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

MEDETOMIDINE HYDROCHLORIDE (86347-15-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

Not Applicable

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

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Medetomidine hydrochloride	86347-15-1	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 2	GHS06, Dgr	H300
2	Acute Tox. 2, Acute Tox. 3, Eye Irrit. 2, Repr. 2, Lact.	GHS06, Dgr, GHS08	H300, H319, H361d, H362, H311, H331
1	Acute Tox. 4	GHS07, Wng	H302, H312, H332
2	Acute Tox. 4	GHS07, Wng	H302, H312, H332

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

Safety Data Sheet

Product Name: Sedator® (1.0 mg/ml solution for injection for cats and dogs)

Issue Date: 07/2017

Version No: 1

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Australia - AICS	N (medetomidine hydrochloride)
Canada - DSL	N (medetomidine hydrochloride)
Canada - NDSL	N (medetomidine hydrochloride)
China - IECSC	N (medetomidine hydrochloride)
Europe - EINEC / ELINCS / NLP	N (medetomidine hydrochloride)
Japan - ENCS	N (medetomidine hydrochloride)
Korea - KECI	N (medetomidine hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	N (medetomidine hydrochloride)
USA - TSCA	N (medetomidine hydrochloride)
Legend:	<i>Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>

SECTION 16: OTHER INFORMATION

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

Full text Risk and Hazard codes:

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H332	Harmful if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H361d	Suspected of damaging the unborn child.
H362	May cause harm to breast-fed children.

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

EN 166 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

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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