

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Atipam® (5.0 mg/g Solution for Injection)
Synonyms:	Revazol [NO, ES, PT]
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:	Atipamezole hydrochloride is a selective α 2-antagonist and is indicated for reversal of the sedative effects of medetomidine and dexmedetomidine in cats and dogs.
Uses advised against:	The product should not be used in: <ul style="list-style-type: none"> • Breeding animals • Animals suffering from liver- or renal diseases The safety of the product has not been documented adequately during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Eurovet Animal Health BV
Address:	Handelsweg 25 5531 AE Bladel The Netherlands
Telephone:	+31 (0) 497 544 300
Fax:	+31 (0) 497 544 302
Email:	Not available
1.4 Emergency Telephone Numbers	
	+31 (0) 497 544 300

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Not considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes.	
DSD Classification (EU):	Not Available
DPD Classification (EU)¹:	Not Available

Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	Not Applicable
2.2 Label Elements	
Signal Word:	NOT APPLICABLE
Hazard Statement(s)	
Not Applicable	
Additional Statement(s)	
Not Applicable	
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	
Inhalation and / or skin contact can cause serious health damage *. May cause eye, respiratory and skin irritation *.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. 104075-48-1 2. Not Available 3. Not Available 4. Not Available	5%	Atipamezole hydrochloride (equivalent to 4.27mg atipamezole base)	Acute toxicity (oral) category 3; H301 ¹
N/a	Proprietary	Other ingredients	N/a

		determined not to be hazardous	
Legend:	1. Classified by Chemwatch		

SECTION 4: FIRST AID MEASURES	
4.1 Description of first aid measures	
Eye contact:	Due to the potent pharmacological activity of atipamezole, skin, eye and mucous membrane contact with this product should be avoided. In case of accidental contact of the product with the eyes rinse abundantly with fresh water. Seek medical attention if irritation persists.
Skin contact:	Due to the potent pharmacological activity of atipamezole, skin, eye and mucous membrane contact with this product should be avoided. In case of accidental contact of the product with the skin rinse abundantly with fresh water. Seek medical attention if irritation persists. Remove contaminated clothes that are in direct contact with the skin.
Inhalation:	Due to physical form of this product, inhalation exposure is unlikely. However, if this product causes irritation to the mucous membranes, seek medical attention.
Ingestion:	Due to the potent pharmacological activity of atipamezole, skin, eye and mucous membrane contact with this product should be avoided. In case of accidental ingestion, seek medical attention if irritation persists.
Self-injection:	Care should be taken to avoid accidental ingestion or self-injection. In case of accidental ingestion or self-injection, seek medical advice immediately and show the package leaflet to the physician.
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	
Treat symptomatically.	

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media	
Suitable:	Water spray, carbon dioxide, dry chemical and foam, as appropriate for surrounding fire and materials.
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. 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:	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:	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. Large spills should be collected into an appropriate container for waste disposal.

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. Observe manufacturer's storage and handling recommendations.
Other Information:	Protect from light. 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: 3 years. Shelf-life after first opening the immediate packaging: 28 days.
Storage incompatibility:	Unknown.

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:

Not Available

EMERGENCY LIMITS:

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
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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: Atipam®: Clear, colourless solution
Container: Cardboard box with 1 clear glass type I vial of 5, 10 or 20ml, with a teflon coated halogenated rubber stopper and aluminium cap.
Physical state: Atipam®: liquid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: In water – no flash point.
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: Atipamezole hydrochloride: 248.75
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. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur.
10.4 Conditions to avoid:	See Section 7.
10.5 Incompatible materials:	See section 7.

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

Inhalation:	There is some evidence that suggests that this substance may cause respiratory irritation to some people. Due to physical form of this product, inhalation exposure is unlikely.	
Ingestion:	This product may cause irritation to the mucous membranes. Significant oral exposure is considered unlikely.	
Skin contact:	The product may produce skin irritation in some persons.	
Eye contact:	The product may produce eye irritation in some persons.	
Chronic:	<p>A transient hypotensive effect has been observed during the first 10 minutes post-injection of atipamezole hydrochloride. In rare cases hyperactivity, tachycardia, salivation, atypical vocalisation, muscle tremor, vomiting, increased respiratory rate, uncontrolled urination and uncontrolled defecation may occur. In very rare cases recurrence of sedation may occur or the recovery time may not be shortened after administration of atipamezole.</p> <p>Overdose of atipamezole hydrochloride may result in transient tachycardia and over-alertness (hyperactivity, muscle tremor). If necessary, these symptoms may be reversed by a medetomidine hydrochloride dose which is lower than the usually used clinical dose.</p>	
Atipam®:	Acute toxicity	Irritation
	Not Available	Not Available
Atipamezole hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 80 mg/kg*e ¹	Eye: moderate Skin: moderate

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

Acute toxicity:
Not Available
Skin corrosion/ irritation:
Not Available
Serious eye damage/ irritation:
Not available

SECTION 11: TOXICOLOGICAL INFORMATION
Respiratory or skin sensitization:
Not available
Germ cell mutagenicity:
Not available
Carcinogenicity:
Not available
Reproductive toxicity:
Not available
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

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.
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Waste Treatment Options:	Not Available
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Sewage Disposal Options:	Not Available
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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	
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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 bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

SECTION 15: REGULATORY INFORMATION

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

ATIPAMEZOLE HYDROCHLORIDE (104075-48-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

N/a

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

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Atipamezole Hydrochloride	15318-45-3	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. 3	GHS06, Dgr	H301, H311, H331
2	Acute Tox. 3	GHS06, Dgr	H301, H311, H331

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

Australia - AICS	N (atipamezole hydrochloride)
Canada - DSL	N (atipamezole hydrochloride)
Canada - NDSL	N (methyl paraben; water; sodium chloride, atipamezole hydrochloride)
China - IECSC	N (atipamezole hydrochloride)
Europe - EINEC / ELINCS / NLP	N (atipamezole hydrochloride)
Japan - ENCS	N (methyl paraben; sodium chloride; atipamezole hydrochloride)
Korea - KECI	N (atipamezole hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	N (atipamezole hydrochloride)
USA - TSCA	N (atipamezole 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.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H360D	May damage the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure
H412	Harmful to aquatic life with long lasting effects.

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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