

SECTION 1: IDENTIFICATION

1.1 Product identifier	
Product name:	Atipam® (5.0 mg/ml 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:	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
Website	www.dechra.com
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	
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	0.5	Atipamezole hydrochloride (equivalent to 4.27mg atipamezole base)	Acute toxicity (oral) category 3; H301 ¹

1. 99-76-3 2. 202-785-7 3. Not available 4. 01-2119463264-40-XXXX/01-2120065912-54-XXXX	0.1	Methyl parahydroxybenzoate	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Chronic Aquatic Hazard Category 2; H315, H319, H335, H411 [1]
N/a	Proprietary	Other ingredients	N/a
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. Prevent, by any means available, spillage from entering drains or water courses.
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:	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
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 available
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	
<p>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): Atipamezole hydrochloride Melting Point 220 degrees C 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</p>	
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:	See section 7.
10.4 Conditions to avoid:	See Section 7.

10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	Due to the potent pharmacological activity of atipamezole, skin, eye- and mucous membrane- contact with this product should be avoided.	
Ingestion:	Care should be taken to avoid accidental ingestion or self-injection. Due to the potent pharmacological activity of atipamezole, skin, eye- and mucous membrane- contact with this product should be avoided .	
Skin contact:	unlikelyCare should be taken to avoid accidental ingestion or self-injection. Due to the potent pharmacological activity of atipamezole, skin, eye- and mucous membrane- contact with this product should be avoided .	
Eye contact:	Due to the potent pharmacological activity of atipamezole, skin, eye- and mucous membrane- contact with this product should be avoided .	
Chronic:	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 minimized as a matter of course	
Atipam®:	Acute toxicity	Irritation
	Not Available	Not Available
Atipamezole hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 80 mg/kg* ¹	Eye: moderate Skin: moderate
Methyl paraben	Toxicity	Irritation
	Oral (rat) LD ₅₀ : 2100 mg/kg* ¹	Not Available

SECTION 11: TOXICOLOGICAL INFORMATION

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

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

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Atipamezole hydrochloride	Not Available	Not Available	Not Available	Not Available	Not Available

Methyl paraben	EC50	48	Crustacea	41.1mg/L	1
Methyl paraben	NOEC	504	Crustacea	0.2mg/L	2
Legend:	<i>Extracted from 1. US EPA, Ecotox database – Aquestic toxicity Data 2. Europe ECHA Registered Substances -</i>				
12.2 Persistence and degradability					
Ingredient		Persistence: Water/Soil		Persistence: Air	
Methyl paraben		LOW		LOW	
12.3 Bioaccumulative potential					
Ingredient			Bioaccumulation		
Methyl paraben			LOW (LogKOW = 1.96)		
12.4 Mobility in Soil					
Ingredient			Mobility		
Methyl paraben			LOW (LogKOW = 125.6)		
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:	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p>
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	
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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			
METHYL PARABEN (99-76-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS:			
EU European Chemicals Agency (ECHA) Community Rolling Action Plan (CoRAP) List of Substances European Customs Inventory of Chemical Substances ECICS (English)			
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	104075-48-1	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. 3	GHS06, Dgr	H301, H311, H331
Ingredient	CAS number	Index Number	ECHA Dossier
Methyl paraben	99-76-3	Not Available	Not Available
Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Irrit. 2; Eye Irrit. 2; STOT SE 3	GHS07; Wng	H315; H319; H335
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; 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.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H360D	May damage the unborn child.
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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