



<b>SECTION 1: IDENTIFICATION</b>	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Domidine® (Solution for Injection 10mg/ml)
<b>Synonyms:</b>	Not Available
<b>Proper Shipping name:</b>	Not Available
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	Sedation and slight analgesia
<b>Uses advised against:</b>	Not for human use.
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name:</b>	Eurovet Animal Health BV
<b>Address:</b>	Handelsweg 25 5531 AE Bladel The Netherlands
<b>Telephone:</b>	+31 (0) 497 544 300
<b>Fax:</b>	+31 (0) 497 544 302
<b>Email:</b>	Not available
<b>Distributor name (Canada):</b>	Dechra Veterinary Products
<b>Address:</b>	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada
<b>Telephone:</b>	+1 (855) 332-9334
<b>Website:</b>	www.dechra.ca
<b>Email:</b>	Not Available
<b>1.4 Emergency Telephone Numbers</b>	
<b>Dechra (EU) :</b>	+31 (0) 497 544 300
<b>Dechra (CA) :</b>	+1 (855) 332-9334



SECTION 2: HAZARDS IDENTIFICATION	
<b>2.1 Classification of the substance or mixture</b>	
<p style="color: red;">This product is exempted from Regulation according to article 1(5) of Reg. (EC) No 1272/2008 and their amendments, because it is a veterinary medicinal products as defined in Directive 2001/82/EC, which is in the finished state, intended for the final user.            Not classified as Dangerous Goods for transport purposes (EU).</p>	
<b>2.1 Classification of the substance or mixture</b>	
<b>DSD Classification (EU):</b>	Not Available
<b>DPD Classification (EU)<sup>1</sup>:</b>	Not Available
<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	None
<b>2.2 Label Elements</b>	
<b>Signal Word:</b>	Not Applicable
<b>Hazard statement(s):</b>	
Not Available	
<b>Precautionary Statement(s) Prevention:</b>	
Not Available	
<b>Precautionary Statement(s) Response:</b>	
Not Available	
<b>Precautionary Statement(s) Storage:</b>	
Not Available	
<b>Precautionary Statement(s) Disposal:</b>	
Not Available	
<b>2.3 Other Hazard Information</b>	

SECTION 3: INFORMATION ON THE INGREDIENTS			
<b>3.1 Substances</b>			
See section below for composition of mixtures			
<b>3.2 Mixtures</b>			
1.CAS No 2.EC Number 3.3.Index Number 4.4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 90038-01-0 2. Not Available 3. Not Available 4. Not Available	1	Detomidine Hydrochloride	Acute Toxicity (oral) Category 4; H302 <sup>1</sup>
Not applicable	Balance	Proprietary information. Ingredients determined not to be hazardous	Not applicable
<b>Legend:</b>		1. Classified by Chemwatch; 2. Classification drawn from EC Directive 67/548/EEC - Annex I	

SECTION 4: FIRST AID MEASURES	
<b>4.1 Description of first aid measures</b>	
<b>Eye contact:</b>	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.
<b>Skin contact:</b>	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.
<b>Inhalation:</b>	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.
<b>Ingestion:</b>	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.
<b>Self-injection:</b>	Care should be taken when handling the product to avoid self-injection. If accidentally self-injected, seek medical advice immediately and show the package leaflet or the label to the medical practitioner but DO NOT DRIVE as sedation and changes in blood pressure may occur. Special caution should be observed by pregnant women. Read the package leaflet before use for full instructions and user warnings.

**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**

Advice to doctors: Detomidine 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.

**SECTION 5: FIRE FIGHTING MEASURES**

**5.1 Extinguishing media**

<b>Suitable:</b>	Select extinguishing media suitable for surrounding area.
<b>Unsuitable:</b>	There is no restriction on the type of extinguisher which may be used.

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

<b>Fire incompatibility:</b>	None known.
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**5.3 Special protective actions for fire-fighters:**

<b>Firefighting:</b>	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.
<b>Fire / explosion hazard:</b>	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**

For information on protective equipment, see section 8

**6.2 Environmental Precautions**

See section 12

**6.3 Methods and material for containment and cleaning up**

<b>Minor Spills:</b>	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.
<b>Major Spills:</b>	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**

<b>Safe Handling:</b>	Wear suitable protection gloves and clothing when handling the product. When handling, <b>DO NOT</b> eat, drink or smoke. Always wash hands with water after handling. <b>In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.</b> 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.
<b>Other Information:</b>	Keep out of the reach and sight of children.

**7.2 Conditions for safe storage, including any incompatibilities**

<b>Suitable Container:</b>	Glass vials 5, 10 and 20 ml with rubber stopper and aluminum cap.
<b>Storage incompatibility:</b>	None known.

**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
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Not Available

**EMERGENCY LIMITS:**

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
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Not Available

Ingredient	Original IDLH	Revised IDLH
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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



<b>Respiratory protection:</b>	Not applicable
<b>8.3 Environmental exposure controls</b> See Section 12	
<b>SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>9.1 Information on basic physical and chemical properties</b>	
<p><b>Appearance:</b> Domidine®: Clear and colourless solution  <b>Container:</b> 5, 10 and 20 ml colourless glass vials with rubber stopper and aluminium cap.  <b>Physical state:</b> Domidine®: Liquid  <b>Odour:</b> Not available  <b>Odour Threshold:</b> Not available  <b>pH (as supplied):</b> Not available  <b>Melting point / freezing point (degrees C):</b> Not available  <b>Initial boiling point and boiling range:</b> Not available  <b>Flash Point:</b> In water – no flash point  <b>Evaporation rate:</b> Not available  <b>Flammability:</b> Not available  <b>Upper/lower flammability or explosive limits:</b> Not available  <b>Vapour pressure:</b> Not available  <b>Relative Density (at degrees C):</b> Not available  <b>Solubility in water and solvents (mg/l):</b> Detomidine Hydrochloride is soluble in water; freely soluble in alcohol; practically insoluble in acetone  <b>Vapour density:</b> Not available  <b>Auto ignition temperature (degrees C):</b> Not available  <b>Decomposition temperature (degrees C):</b> Not available  <b>Viscosity: (degrees C):</b> Not available  <b>Explosive properties:</b> Not available  <b>Oxidising properties:</b> Not available  <b>Partition Coefficient:</b> Not available  <b>Molecular weight:</b> Detomidine hydrochloride: 222.71 g/mol  <b>Taste:</b> Not available  <b>Surface tension:</b> Not available  <b>Volative component:</b> Not available  <b>Gas group:</b> Not available  <b>pH as a solution:</b> Not available  <b>VOC g/L:</b> Not available</p>	
<b>9.2 Other information</b> 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.

SECTION 11: TOXICOLOGICAL INFORMATION	
<b>Inhalation:</b>	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.
<b>Ingestion:</b>	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 <b>DO NOT DRIVE</b> as sedation and changes in blood pressure may occur.
<b>Skin contact:</b>	Although the liquid is not thought to be an irritant (as classified by EC Directives), irritation, sensitization, contact dermatitis and systemic effects cannot be excluded after skin contact.
<b>Eye contact:</b>	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterized by tearing or conjunctival redness (as with windburn).
<b>Chronic:</b>	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Based on experience with similar materials, there is a possibility that exposure to the material may reduce fertility in humans at levels which do not cause other toxic effects.  Detomidine 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.





**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>Self-injection:</b>	In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician but <b>DO NOT DRIVE</b> as sedation and changes in blood pressure may occur. 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
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<b>Domidine®:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Detomidine 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.	Not Available
<b>Detomidine hydrochloride:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (rat) LD50: 60 mg/kg <sup>1</sup>	Not available

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

<b>Skin corrosion/ irritation:</b>
Not Available
<b>Serious eye damage/ irritation:</b>
Not Available
<b>Respiratory or skin sensitization:</b>
Not Available
<b>Germ cell mutagenicity:</b>
Not Available
<b>Carcinogenicity:</b>
Not Available



<b>Reproductive toxicity:</b>
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.
<b>STOT – single exposure:</b>
Not Available
<b>STOT–repeated exposure:</b>
Not Available
<b>Aspiration hazard:</b>
Not Available

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Detomidine Hydrochloride	LC <sub>50</sub>	96	Fish	0.490mg/L	1
Detomidine Hydrochloride	EC <sub>50</sub>	96	Algae or other aquatic plants	0.595mg/L	1
<b>Legend:</b>	1. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated)				

**DO NOT** discharge into sewer or waterways.

### 12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Detomidine Hydrochloride	HIGH	HIGH

### 12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
Detomidine Hydrochloride	MEDIUM (LogKOW = 4.4607)

### 12.4 Mobility in Soil

Ingredient	Mobility
Detomidine Hydrochloride	LOW (KOC = 16740)



<b>12.5 Results of PBT and vPvB assessment</b> Not Available
<b>12.6 Other adverse effects</b> Not Available

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	
<b>Product / packaging disposal:</b>	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 Products Regulations (Canada, 2015).
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

**SECTION 14: TRANSPORT INFORMATION**

<b>Labels required:</b>	
<b>Marine pollutant:</b>	NO
<b>Hazchem:</b>	Not Applicable
<b>Land transport (EU: ADR / US: DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	

**SECTION 15: REGULATORY INFORMATION**

<b>15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture</b>
<b>DETOMIDINE HYDROCHLORIDE (90038-01-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS:</b>
<ul style="list-style-type: none"> <li>European Customs Inventory of Chemical Substances ECICS (English)</li> </ul>



15.2 Chemical Safety Assessment			
ECHA SUMMARY			
Ingredient	CAS number	Index Number	ECHA Dossier
Detomidine hydrochloride	90038-01-0	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, Wng	H301, 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

National Inventory	Status
Australia – AICS	N (Detomidine hydrochloride)
Canada – DSL	N (Detomidine hydrochloride)
Canada – NDSL	N (Detomidine hydrochloride)
China – IECSC	N (Detomidine hydrochloride)
Europe - EINEC / ELINCS / NLP	N (Detomidine hydrochloride)
Japan – ENCS	N (Detomidine hydrochloride)
Korea – KECI	N (Detomidine hydrochloride)
New Zealand – NZIoC	Y
Philippines – PICCS	N (Detomidine hydrochloride)
USA – TSCA	N (Detomidine hydrochloride)
Taiwan - TSCI	N (Detomidine hydrochloride)
Mexico - INSQ	N (Detomidine hydrochloride)
Vietnam – NCI	N (Detomidine hydrochloride)
Russia - ARIPS	N (Detomidine hydrochloride)
<b>Legend:</b>	<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, OSHA and ECHA.

### Full text Risk and Hazard codes:

<b>H301</b>	Toxic if swallowed.
<b>H302</b>	Harmful if swallowed.
<b>H311</b>	Toxic in contact with skin.
<b>H312</b>	Harmful in contact with skin.
<b>H331</b>	Toxic if inhaled.
<b>H332</b>	Harmful if inhaled.

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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