## Complying to Regulation (EC) 1907/2006

# Material Safety Data Sheet Detonervin 10mg/ml solution for injection



# SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

**Product name(s):** Detonervin 10mg/ml solution for injection

Product code(s): XVD136 (5 ml)

XVD137 (10 ml)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Veterinary medicinal product

**Uses advised against:** Not for human use. Refer to the product information leaflet

Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

**Company name:** Animalcare Limited **Address:** 10 Great Northway

York Business Park Nether Poppleton

York YO26 6RB United Kingdom

1.4 Emergency telephone number

**Daytime:** +44 (0) 1904 487687

## **SECTION 2: HAZARDS IDENTIFICATION**

## 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008

This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to

point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

**Labelling according to Regulation** 

(EC) 1272/2008

This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according

to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms:

Signal word:

Hazard statements:

Precautionary statements:

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

2.3 Other hazards

Hazard(s) not otherwise

classified (HNOC)

None known

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2 Mixtures

Substance name in the mixture	CAS No	Quantity
Medetomidine HCl	[90038-01-0]	1%
Methyl parahydroxybenzoate	[99-76-3]	0.1%
Sodium chloride	[7647-14-5]	Proprietary
Water	[7732-18-5]	Proprietary

## **SECTION 4: FIRST AID MEASURES**

## 4.1 Description of first aid measures

Eyes: In the case of accidental contact of the product with eyes, rinse abundantly with

fresh water. If symptoms occur, seek the advice of a physician

**Skin:** Avoid skin contact. Wash the exposed skin immediately after exposure with large

amounts of water. Remove contaminated clothes that are in direct contact with

skin

**In the case of accidental oral intake, seek medical advice immediately and show the** 

package insert to the physician but DO NOT DRIVE as sedation and changes in blood

pressure may occur

**Injection:** In the case of accidental self-injection, seek medical advice immediately and show

the package insert to the physician but DO NOT DRIVE as sedation and changes in

blood pressure may occur

## 4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

## 4.3 Indication of any immediate medical attention and special treatment needed

No specific measures identified. Seek medical advice if required

# **SECTION 5: FIRE- FIGHTING MEASURES**

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the

surrounding environment

Unsuitable extinguishing media: None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during

firefighting:

Not flammable or combustible

Hazardous combustion products: Decomposition products may include the following materials: Carbon oxides (CO<sub>x</sub>),

nitrogen oxides (NO<sub>x</sub>)

5.3 Advice for fire-fighters

Special protective equipment for

firefighters:

Use personal protective equipment

Further information: Fire residues and contaminated fire extinguishing water must be disposed of in

accordance with local regulations

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency

personnel:

Refer to protective measures listed in sections 7 and 8

Advice for emergency responders: If specialised clothing is required to deal with the spillage, take note of any

information is section 8 on suitable and unsuitable materials

#### 6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water of drains. Do not allow to enter into soil/subsoil.

## 6.3 Methods and material for containment and cleaning up

Large spills: Dike spilled material or otherwise contain material to ensure runoff does not reach

a waterway

Small spills: Stop leak if safe to do so. Contain spillage, and then collect with non-combustible

absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

Flush away traces with water

#### 6.4 Reference to other sections

See Section 1 for emergency contact information

See section 8 for personal protection

See Section 13 for additional waste treatment information

#### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Advice on safe handling: When handling pharmaceutical products, avoid all contact and inhalation of dust,

fumes, mist, and/or vapours associated with the product

**Hygiene measures:** No specific measures identified

## 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas

and containers:

Keep out of reach of children. Keep in the original packaging

Storage temperature:
Further information on storage

conditions:

Protect from direct incidence of light

Store above 5 °C. Do not freeze

## 7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

## 8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. Data not known.

#### 8.2 Exposure controls

Engineering measures: Good general ventilation should be sufficient to control worker exposure to

airborne contaminants

Individual protection measures:

**Hygiene measures:** No specific measures identified

**Eye/face protection:** Safety glasses or goggles recommended

**Skin/body protection:** Disposable garments if direct skin contact is anticipated

**Hand protection:** Disposable latex gloves recommended

**Respiratory protection:** With satisfactory ventilation, respiratory protection is usually not required

**Environmental exposure controls:** Consider the provision of containment around storage vessels

## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

## 9.1 Information on basic physical and chemical properties

Appearance Liquid

Colour: Clear, colourless

Odour: None

**Odour threshold:** No data available No data available :Ha Density: No data available Melting point: No data available **Boiling point:** No data available Flash point: No data available **Evaporation rate:** No data available Flammability: No data available

Water solubility: Soluble

Partition coefficient:

Auto-ignition temperature:

No data available

Thermal decomposition:

No data available

Viscosity:

No data available

Vapour pressure:

No data available

Vapour density:

No data available

Explosive properties:

No data available

Oxidizing properties: The substance or mixture is not classified as oxidizing

#### 9.2 Other information

No data available.

#### **SECTION 10: STABILITY AND REACTIVITY**

#### 10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

#### 10.2 Chemical stability

Stable under normal conditions

#### 10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

#### 10.4 Conditions to avoid

Avoid contact with incompatible materials

## 10.5 Incompatible materials

None Known

## 10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

#### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity: Medetomidine HCl LD<sub>50</sub> 3200 mg/kg (Rabbit, oral)

Medetomidine HCl LD<sub>50</sub> 980 mg/kg (Rat, oral)

Chronic toxicity: No data available

Skin irritation/sensitization: Medetomidine HCl – Draize test (Rabbit eye) - Moderate

Reproductive toxicity: No data available

Carcinogenicity: No indication of human carcinogenicity

Mutagenicity: No data available

## **SECTION 12: ECOLOGICAL INFORMATION**

## 12.1 Toxicity

No data available

## 12.2 Persistence and degradability

No data available

#### 12.3 Bioaccumulative potential

No data available

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

No data available

## 12.6 Other adverse effects

No data available

#### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

# **SECTION 14: TRANSPORT INFORMATION**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

## **SECTION 15: REGULATORY INFORMATION**

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

This product has been authorised under the provisions of Directive 2001/82/EC

#### 15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

# **SECTION 16: OTHER INFORMATION**

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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