

Material Safety Data Sheet**Anaestamine 100 mg/ml Solution for Injection****SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING****1.1 Product identification**

Product name(s):	Anaestamine 100 mg/ml Solution for Injection
Product code(s):	XVD 010 (10 ml vial) XVD 012 (50 ml vial)

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
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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.
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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:	Not applicable
Signal word:	Not applicable
Hazard statements:	Not applicable
Precautionary statements:	Not applicable
Supplemental information:	Hypersensitivity to the material and/or similar materials. Preexisting ailments in the following organs: eyes, skin, gastrointestinal system, cardiovascular system, respiratory system

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC)	None known
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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Ketamine hydrochloride	[1867-66-9]	10%
Chlorocresol	[59-50-7]	0.1%
Sodium hydroxide	[1310-73-2]	Proprietary
Water	[7732-18-5]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes:	Avoid contact with the eyes. Wash any splashes from skin and eyes immediately with large amounts of water. If symptoms occur after ocular contact, seek medical advice immediately and show the package leaflet or the label to the physician, but DO NOT DRIVE.
Skin:	Avoid contact with the skin. Wash any splashes from skin and eyes immediately with large amounts of water
Ingestion:	If symptoms occur after oral contact, seek medical advice immediately and show the package leaflet or the label to the physician, but DO NOT DRIVE
Injection:	In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician, but DO NOT DRIVE

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 _x), nitrogen oxides (NO _x)

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 in 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 or 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 vapors associated with the product

Hygiene measures: None 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: Store below 25 °C

Further information on storage conditions: Protect from direct incidence of light. Store the vial upright

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.

Not established.

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
pH:	No data available
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:	No data available
Partition coefficient:	No data available
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:	Ketamine hydrochloride LD ₅₀ 447-670 mg/kg (Rat, oral) Ketamine hydrochloride LD ₅₀ 617 mg/kg (Mouse, oral) Ketamine hydrochloride LD ₅₀ 58.9 mg/kg (Rat, IV)
Chronic toxicity:	Ketamine hydrochloride NOAEL 10 mg/kg/day (Rat, IV) Ketamine hydrochloride NOAEL 40 mg/kg/day (Dog, IM)
Skin irritation/sensitization:	No data available
Reproductive toxicity:	Ketamine hydrochloride NOAEL 60 mg/kg/day (Rat, IV) Ketamine hydrochloride NOAEL 120 mg/kg/day (Rat, IM)
Carcinogenicity:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Mutagenicity:	ketamine hydrochloride (Ames): Salmonella, E. coli Negative

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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