Complying to Regulation (EC) 1907/2006

Material Safety Data Sheet
Frusecare 40 mg Tablets

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

1.1 Product identification

Product name(s): Frusecare 40 mg Tablets
Product code(s): XVD 485

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: Not applicable
Signal word: Not applicable
Hazard statements: Not applicable
Precautionary statements: Not applicable
Supplemental information: 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*
Furosemide	[54-31-9]	40 mg/tablet
Maize starch	[9005-25-8]	Proprietary
Pregelatinized maize starch	[9057-07-2]	Proprietary
Magnesium stearate	[557-04-0]	Proprietary
Lactose monohydrate	[5989-81-1]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes: In case of eye contact Rinse abundantly with fresh water

Skin: In case of skin contact wash the exposed skin immediately after exposure with large amounts of water. Remove contaminated clothes that are in direct contact with skin. Rinse with water

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: This route of exposure is unlikely. Get medical attention is symptoms occur

4.2 Most important symptoms and effects, both acute and delayed

Signs and symptoms might include nausea, vomiting, cramps, dizziness, headache, vertigo, low blood pressure on standing, rash, urticaria, photosensitivity, electrolyte imbalance, muscle spasm, weakness, and restlessness. Hypersensitivity reactions may also occur in susceptible individuals. Effects on blood and blood-forming organs have also occurred. May cause adverse effects on the developing fetus

4.3 Indication of any immediate medical attention and special treatment needed

See patient package insert in shipping carton for complete information.
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 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

Small spills: Wear recommended personal protective equipment (see section 8- Exposure controls/personal Protection). Use absorbent towels or brooms to clean up spill. Wipe surface area clean with soap and water

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

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment

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. Keep container tightly closed

Storage temperature: Store below 25 ^{o}C

Further information on storage conditions: Keep in a dry, cool and well-ventilated place

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. At this time, the other constituents have no known exposure limits

Substance name in the mixture	*Type*	*Value*
Magnesium stearate	TWA	10 mg/m^3
Maize starch	TWA	10 mg/m^3

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: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent)

Skin/body protection: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent)

Hand protection: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent)

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	Solid tablet
Colour:	White
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:	Furosemide LD_{50} 2600 mg/kg (Rat, oral)
Chronic toxicity:	Furosemide LOAEL 30 mg/kg/day (Rat, oral, 2 years)
Skin irritation/sensitization:	No data available
Reproductive toxicity:	Furosemide LOAEL 2.9 mg/kg/day (Rat, oral) Fertility
Carcinogenicity:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data
Mutagenicity:	Furosemide Bacterial Mutagenicity (AMES) negative Furosemide Mammalian cell mutagenicity (Mouse lymphoma) positive

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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