Complying to Regulation (EC) 1907/2006

Material Safety Data Sheet
Cephacare Flavour Tablets 50/250/500/1000 mg

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

1.1 Product identification

Product name(s): Cephacare Flavour 50 mg Tablets for Cats and Dogs
Cephacare Flavour 250 mg Tablets for Dogs
Cephacare Flavour 500 mg Tablets for Dogs
Cephacare Flavour 1000 mg Tablets for Dogs

Product code(s): XVD730, XVD731 (50 mg tablets)
XVD733, XVD734 (250 mg tablets)
XVD736, XVD737 (500 mg tablets)
XVD738UK (1000 mg tablets)

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
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) Cephacare flavour tablets present little or no danger to either man or the environment under normal conditions of use.
Note; Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may

lead to cross-reactions to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised or if you have been advised not to be in contact with such substances.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure such as skin rash you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Substance name in the mixture	*CAS No*	*Quantity*
Cephalexin monohydrate	[23325-78-2]	50 – 75 %
Lactose monohydrate	[64044-51-5]	Proprietary
Potato starch	[9005-25-8]	Proprietary
Magnesium stearate	[557-04-0]	Proprietary
Beef flavour	N/A	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes: Holding eyelids apart rinse immediately with copious amounts of clean water for at least 15-20 minutes

Skin: Wash hands immediately after use with plenty of soap and water

Ingestion: If accidentally ingested wash out mouth, give plenty of water or bland fluids to drink. Seek immediate medical treatment

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

Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. Protect the patient's airway and support ventilation and perfusion. Serious acute hypersensitivity reactions may require the use of subcutaneous epinephrine and other emergency measures. Anticonvulsant therapy can be given if clinically indicated in event of seizures.

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product

Unsuitable extinguishing media: None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: This material must be substantially pre-heated before ignition can occur

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: Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters.

Further information: If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Procedures for clean up: Wear rubber or PVC gloves if there is a risk of personal contact with the product. If there is a risk of generating airborne dust, a dust mask e.g. conforming to BS 2091 may be necessary. Tablets should be swept up avoiding the generation of airborne dust (e.g. by covering the spill with damp sand), collected and placed in a closed container

Disposal: containers of this waste should be collected by a registered contractor for safe disposal e.g. by incineration or deep burial at an approved location. The local authority should be able to provide further advice in this respect

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

Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

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: Pick-up or wipe-up spilled tablets with damp absorbent sheets to prevent generation of dusts. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean 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: Do not handle if you know you are sensitised to penicillin or cephalosporins or if you have been advised not to work with such preparations

Hygiene measures: Wash hands after use

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 ^{o}C in a dry place

Further information on storage conditions: Protect from direct incidence of light

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*
Cephalexin monohydrate	TWA	10 mg/m^3
Magnesium stearate	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: No specific measures identified

Skin/body protection: No specific measures identified

Hand protection: Suitable rubber gloves should be word if cuts and scratches are present on hands

Respiratory protection: None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements (89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.

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 Tablets

Colour: Beige

Odour: Artificial beef

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:	Cephalexin monohydrate LD_{50} >5000 mg/kg (Rat, oral) Cephalexin monohydrate LD_{50} 1000 mg/kg (Monkey, oral) Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. This can result in symptoms such as skin rash in which case you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention
Chronic toxicity:	No chronic effects have been reported from workplace exposure. It is anticipated that for Occupational Exposure the target organs are: Acute: Skin, eyes, respiratory system. Chronic: Skin
Skin irritation/sensitization:	No data available
Reproductive toxicity:	There are no adequate and well-controlled studies of Cephalexin in pregnant women; however, when administered therapeutically, Cephalexin is not expected to cause fetal harm when administered to a pregnant woman. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category B. Refer to Definition of Terms for full Pregnancy Risk category definitions. Reproduction studies have been performed on mice and rats using oral doses of Cephalexin Monohydrate 0.6 and 1.5 times the maximum daily human dose (66 mg/kg/day) based upon mg/m2, and have revealed no harm to the fetus
Carcinogenicity:	Lifetime studies in animals have not been performed to evaluate the carcinogenic potential of Cephalexin
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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