

# Material Safety Data Sheet

## Cephacare Flavour Tablets 50/250/500 mg

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

#### 1.1 Product identification

<b>Product name(s):</b>	Cephacare Flavour 50 mg Tablets for Cats and Dogs Cephacare Flavour 250 mg Tablets for Dogs Cephacare Flavour 500 mg Tablets for Dogs
<b>Product code(s):</b>	XVD730, XVD731 (50 mg tablets) XVD733, XVD734 (250 mg tablets) XVD736, XVD737 (500 mg tablets)

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

<b>Relevant identified uses:</b>	Veterinary medicinal product
<b>Uses advised against:</b>	Not for human use. Refer to the product information leaflet
<b>Reasons why uses advised against:</b>	Refer to the product information leaflet

#### 1.3 Details of the supplier of the safety data sheet

<b>Company name:</b>	Animalcare Limited
<b>Address:</b>	10 Great Northway York Business Park Nether Poppleton York YO26 6RB United Kingdom

#### 1.4 Emergency telephone number

<b>Daytime:</b>	+44 (0) 1904 487687
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### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

<b>Classification according to Regulation (EC) 1272/2008</b>	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

<b>Labelling according to Regulation (EC) 1272/2008</b>	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.
<b>Hazard pictograms:</b>	Not applicable
<b>Signal word:</b>	Not applicable
<b>Hazard statements:</b>	Not applicable
<b>Precautionary statements:</b>	Not applicable
<b>Supplemental information:</b>	Not applicable

#### 2.3 Other hazards

<b>Hazard(s) not otherwise classified (HNOC)</b>	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
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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

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
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

<b>Eyes:</b>	Holding eyelids apart rinse immediately with copious amounts of clean water for at least 15-20 minutes
<b>Skin:</b>	Wash hands immediately after use with plenty of soap and water
<b>Ingestion:</b>	If accidentally ingested wash out mouth, give plenty of water or bland fluids to drink. Seek immediate medical treatment
<b>Inhalation:</b>	This route of exposure is unlikely. Get medical attention if 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

<b>Suitable extinguishing media:</b>	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
<b>Unsuitable extinguishing media:</b>	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<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>)

## 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 in 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 °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

<i>Substance name in the mixture</i>	<i>Type</i>	<i>Value</i>
Cephalexin monohydrate	TWA	10 mg/m <sup>3</sup>
Magnesium stearate	TWA	10 mg/m <sup>3</sup>

### 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 worn 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

<b>Appearance</b>	Tablets
<b>Colour:</b>	Beige
<b>Odour:</b>	Artificial beef
<b>Odour threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Density:</b>	No data available
<b>Melting point:</b>	No data available
<b>Boiling point:</b>	No data available
<b>Flash point:</b>	No data available
<b>Evaporation rate:</b>	No data available
<b>Flammability:</b>	No data available
<b>Water solubility:</b>	No data available
<b>Partition coefficient:</b>	No data available
<b>Auto-ignition temperature:</b>	No data available
<b>Thermal decomposition:</b>	No data available
<b>Viscosity:</b>	No data available
<b>Vapour pressure:</b>	No data available

<b>Vapour density:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	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

<b>Acute toxicity:</b>	Cephalexin monohydrate LD <sub>50</sub> >5000 mg/kg (Rat, oral) Cephalexin monohydrate LD <sub>50</sub> 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
<b>Chronic toxicity:</b>	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
<b>Skin irritation/sensitization:</b>	No data available
<b>Reproductive toxicity:</b>	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/m <sup>2</sup> , and have revealed no harm to the fetus
<b>Carcinogenicity:</b>	Lifetime studies in animals have not been performed to evaluate the carcinogenic potential of Cephalexin
<b>Mutagenicity:</b>	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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