

# Material Safety Data Sheet

## Phenoleptil tablets

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

#### 1.1 Product identification

Product name(s):	Phenoleptil tablets
Product code(s):	XVD 121 (12.5 mg tablets) XVD 016 (25 mg tablets) XVD 123 (50 mg tablets) XVD 018 (100 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 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:	Not applicable

#### 2.3 Other hazards

Hazard(s) not otherwise classified (HNOC)	People with known hypersensitivity to barbiturates should avoid contact with the veterinary medicinal product. Wash hands after use. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the doctor
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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>
Phenobarbital	[50-06-06]	12.5 – 100 mg/tablet
Lactose Monohydrate	[5989-81-1]	Proprietary
Microcrystalline Cellulose	[9004-34-6]	Proprietary
Sodium Starch Glycolate	[9063-38-1]	Proprietary
Silica, Colloidal Anhydrous	[7631-86-9]	Proprietary
Magnesium Stearate	[557-04-0]	Proprietary
Dry Beef Flavour	NA	Proprietary

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Eyes:</b>	In case of eye contact Rinse abundantly with fresh water and seek medical advice
<b>Skin:</b>	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
<b>Ingestion:</b>	In case of accidental ingestion or eye irritation, seek medical help and show the doctor the package insert
<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

See patient package insert in shipping carton for complete information.  
No specific measures identified. Seek medical advice if required

## SECTION 5: FIRE- FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media:</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
<b>Unsuitable extinguishing media:</b>	None known

### 5.2 Special hazards arising from the substance or mixture

<b>Specific hazards during firefighting:</b>	Not flammable or combustible
<b>Hazardous combustion products:</b>	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

<b>Special protective equipment for fire-fighters:</b>	Keep non-essential personnel and unprotected people away. Do not enter fire area without suitable protective equipment. If possible and without risk, cool closed containers exposed to fire with water spray
<b>Further information:</b>	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

**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:** See also the label and /or insert leaflet. See also Section 8

**Hygiene measures:** Wash thoroughly after handling

### 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 between 15-30 °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, none of the other constituents have known exposure limits

### 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)

<b>Skin/body protection:</b>	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)
<b>Hand protection:</b>	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)
<b>Respiratory protection:</b>	Not applicable
<b>Environmental exposure controls:</b>	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>	Solid tablets
<b>Colour:</b>	White to off-white with brown speckles
<b>Odour:</b>	None
<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>	Phenobarbital LD <sub>50</sub> 151 mg/kg (Rat, oral)
<b>Chronic toxicity:</b>	No data available
<b>Skin irritation/sensitization:</b>	No data available
<b>Reproductive toxicity:</b>	No data available
<b>Carcinogenicity:</b>	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data
<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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