

Material Safety Data Sheet

Vitofyllin 50mg and 100mg Tablets

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

1.1 Product identification

Product name(s):	Vitofyllin 50 mg Tablets Vitofyllin 100 mg Tablets
Product code(s):	XVD430 (50 mg tablets) XVD432 (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
----------	---------------------

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

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Propentofylline	[55242-55-2]	25 – 50 %
Lactose monohydrate	[10039-26-6]	Proprietary
Starch	[9005-25-8]	Proprietary
Crospovidone	[9003-39-8]	Proprietary
Talc	[14807-96-6]	Proprietary
Colloidal silica	[7631-86-9]	Proprietary
Magnesium stearate	[557-04-0]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes:	Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open. If there is any redness, pain or visual impairment, consult an ophthalmologist
Skin:	Remove any soiled or splashed clothing immediately. Watch out for any remaining product between skin and clothing, watches, shoes, etc. If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital
Ingestion:	In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water, administer activated medical charcoal and consult a doctor. Seek medical attention, showing the label. If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label
Inhalation:	This route of exposure is unlikely. In the event of massive inhalation of dust, remove the person exposed to fresh air. Keep warm and at rest. If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call a doctor. Do not proceed with mouth-to-mouth or mouth-to-nose resuscitation

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 retrieve the product by mechanical means (sweeping/vacuuming)

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: Always wash hands after handling

Hygiene measures: Remove and wash contaminated clothing before re-using

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 the container tightly closed in a dry, well-ventilated place. Keep away from food and drink, including those for animals

Storage temperature: Store below 25 °C

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>
Starch	TWA	10 mg/m ³
Talc	TWA	1 mg/m ³

8.2 Exposure controls

Engineering measures:	Use personal protective equipment that is clean and has been properly maintained. Store personal protective equipment in a clean place, away from the work area. Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas
Individual protection measures:	
Hygiene measures:	No specific measures identified
Eye/face protection:	Avoid contact with eyes. Before handling powders or dust emission, wear mask goggles in accordance with standard EN166
Skin/body protection:	Avoid skin contact. Wear suitable protective clothing. Suitable type of protective clothing: Wear protective clothing against solid chemicals and particles suspended in the air (type 5) in accordance with standard EN13982-1 to prevent skin contact. Work clothing worn by personnel shall be laundered regularly. After contact with the product, all parts of the body that have been soiled must be washed
Hand protection:	Wear suitable protective gloves in the event of prolonged or repeated skin contact. Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374. Gloves must be selected according to the application and duration of use at the workstation. Protective gloves need to be selected according to their suitability for the workstation in question: other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required. Recommended properties: Impervious gloves in accordance with standard EN374.
Respiratory protection:	Avoid breathing dust. If the ventilation is insufficient, wear appropriate breathing apparatus. When workers are confronted with concentrations that are above occupational exposure limits, they must wear a suitable, approved, respiratory protection device. Type of FFP mask: Wear a disposable half-mask dust filter in accordance with standard EN149. Category: FFP1 Anti-gas and vapour filter(s) (Combined filters) in accordance with standard EN14387: A1 (Brown)
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	Tablet
Colour:	Yellow
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:	Propentofylline LD ₅₀ 405 mg/kg (Rabbit, oral)
Chronic toxicity:	No data available
Skin irritation/sensitization:	No data available
Reproductive toxicity:	No data available
Carcinogenicity:	CAS 14807-96-6: IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans. CAS 7631-86-9: IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans. CAS 9003-39-8: IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans
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

End of document