

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Propentofylline Formulation

Version 4.0      Revision Date: 07/06/2024      SDS Number: 2929978-00017      Date of last issue: 05/16/2024  
Date of first issue: 06/25/2018

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### SECTION 1. IDENTIFICATION

Product name : Propentofylline Formulation  
Other means of identification : Vivitonin (A005114)  
VIVITONIN 50 TABLETS FOR AGED DOGS (51394)  
VIVITONIN 100 TABLETS FOR AGED DOGS (49892)

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Acute toxicity (Oral) : Category 4

Specific target organ toxicity : Category 2  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.  
H373 May cause damage to organs through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
**Response:**  
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.  
P314 Get medical attention if you feel unwell.  
**Disposal:**  
P501 Dispose of contents and container to an approved waste

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disposal plant.

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form combustible dust concentrations in air during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Propentofylline	3,7-Dihydro-3-methyl-1-(5-oxohexyl)-7-propyl-1H-purine-2,6-dione	55242-55-2	$\geq 30 - < 60$ *
Starch	Sago starch	9005-25-8	$\geq 10 - < 30$ *
Talc	Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	$\geq 1 - < 5$ *

\* Actual concentration or concentration range is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed.  
May cause damage to organs through prolonged or repeated exposure if swallowed.  
Contact with dust can cause mechanical irritation or drying of the skin.

Protection of first-aiders : Dust contact with the eyes can lead to mechanical irritation.  
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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### SECTION 7. HANDLING AND STORAGE

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- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propentofylline	55242-55-2	TWA	1000 µg/m <sup>3</sup> ( OEB 1)	Internal
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Talc	14807-96-6	TWAEV (respirable dust)	2 mg/m <sup>3</sup>	CA QC OEL
		TWA (Respirable particulates)	2 mg/m <sup>3</sup>	CA AB OEL
		TWA (Respirable)	2 mg/m <sup>3</sup>	CA BC OEL
		TWA	2 fibres per cubic centimeter	CA ON OEL

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		TWA (Respirable fraction)	2 mg/m <sup>3</sup>	CA ON OEL
		TWA (Respirable particulate matter)	2 mg/m <sup>3</sup>	ACGIH

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

**Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type** : Particulates type

**Hand protection**  
**Material** : Chemical-resistant gloves

**Eye protection** : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat.

**Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : tablet, powder

**Color** : No data available

**Odor** : No data available

**Odor Threshold** : No data available

**pH** : Not applicable

**Melting point/freezing point** : No data available

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Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle characteristics		
Particle size	:	No data available

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### SECTION 10. STABILITY AND REACTIVITY

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Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form combustible dust concentrations in air during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1,880 mg/kg  
Method: Calculation method

#### Components:

##### **Propentofylline:**

Acute oral toxicity : LD50 (Rat): 940 mg/kg  
Symptoms: Breathing difficulties, Convulsions, Lachrymation  
  
LD50 (Mouse): 780 mg/kg  
  
LD50 (Rabbit): 405 mg/kg

##### **Starch:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### **Talc:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Remarks: Based on data from similar materials

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### **Talc:**

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Species : Rabbit  
Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Starch:

Species : Rabbit  
Result : No eye irritation

#### Talc:

Species : Rabbit  
Result : No eye irritation

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Starch:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

#### Talc:

Routes of exposure : Skin contact  
Species : Humans  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Starch:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

#### Talc:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative



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Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Talc:**

Species : Mouse  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Result : negative

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **Propentofylline:**

Effects on fetal development : Test Type: Development  
Species: Mouse  
Application Route: Ingestion  
Developmental Toxicity: NOAEL: 500 mg/kg body weight  
Result: No adverse effects.

Test Type: Development  
Species: Rabbit  
Application Route: Ingestion  
Developmental Toxicity: NOAEL: 150 mg/kg body weight  
Result: No teratogenic effects.

#### **Talc:**

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **STOT-single exposure**

Not classified based on available information.

### **STOT-repeated exposure**

May cause damage to organs through prolonged or repeated exposure if swallowed.

### **Components:**

#### **Propentofylline:**

Routes of exposure : Oral  
Assessment : May cause damage to organs through prolonged or repeated exposure.

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||Remarks : Based on human experience.

### Repeated dose toxicity

#### Components:

##### Starch:

||Species : Rat  
||NOAEL :  $\geq 2,000$  mg/kg  
||Application Route : Skin contact  
||Exposure time : 28 Days  
||Method : OECD Test Guideline 410

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### Propentofylline:

||Ingestion : Target Organs: Blood  
||Target Organs: Lungs  
||Target Organs: Cardiovascular  
||Target Organs: Gastro-intestinal system  
||Symptoms: Gastrointestinal discomfort, Nausea  
||Target Organs: Nervous system  
||Symptoms: Dizziness, Headache

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### Propentofylline:

#### Ecotoxicology Assessment

||Acute aquatic toxicity : Toxic effects cannot be excluded  
||Chronic aquatic toxicity : Toxic effects cannot be excluded

#### Talc:

||Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)):  $> 100,000$  mg/l  
||Exposure time: 24 h

### Persistence and degradability

No data available

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### Bioaccumulative potential

#### Components:

#### Propentofylline:

Partition coefficient: n-octanol/water : log Pow: 1.540

#### Mobility in soil

No data available

#### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

### The ingredients of this product are reported in the following inventories:

DSL : not determined

AICS : not determined

IECSC : not determined

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### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA ON OEL	:	Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA ON OEL / TWA	:	Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV	:	Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8