Signal word



# **Propentofylline Formulation**

Versi 7.0		Revision Date: 06.07.2024		S Number: 9966-00018		sue: 23.05.2024 sue: 25.06.2018	
Sect	ion 1: lo	dentification					
	Product	name	:	Propentofylline F	ormulation		
	Other means of identification		:	Vivitonin (A005114) VIVITONIN 50 TABLETS FOR AGED DOGS (51394) VIVITONIN 100 TABLETS FOR AGED DOGS (49892)			
	Manufa	cturer or supplier's d	letai	ls			
	Compar	лу	:	MSD			
	Address	3	:	33 Whakatiki Stre Upper Hutt - New		g 908	
	Telepho	one	:	0800 800 543			
	Emerge	ncy telephone number	· :	0800 764 766 (08 CHEMCALL)	800 POISON)	0800 243 622 (0800	
	E-mail a	address	:	EHSDATASTEW	ARD@msd.cor	n	
	Recom	mended use of the ch	nemi	ical and restrictio	ons on use		
		nended use ions on use	:	Veterinary produce Not applicable	ct		
Sect	ion 2: H	lazard identification					
	GHS CI	assification					
	Acute to	oxicity (Oral)	:	Category 4			
		target organ toxicity - d exposure (Oral)	:	Category 2			
	GHS lal	bel elements					
	Hazard	pictograms	:		!>		

 Hazard statements
 : H302 Harmful if swallowed.

 H373 May cause damage to organs through prolonged or repeated exposure if swallowed.

 Precautionary statements
 : Prevention:

Warning

:



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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 POISON CENTER/ doctor if you feel unwell. Rinse mouth. P314 Get medical advice/ attention if you feel unwell.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

#### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 50 %

#### Other hazards which do not result in classification

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	CAS-No.	Concentration (% w/w)
Propentofylline	55242-55-2	>= 50 -< 70
Starch	9005-25-8	>= 10 -< 20
Talc	14807-96-6	>= 1 -< 10

#### Section 4: First-aid measures

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice 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



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Protection of first-aiders Notes to physician		<ul> <li>the skin.</li> <li>Dust contact with the eyes can lead to mechanical irritation.</li> <li>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).</li> <li>Treat symptomatically and supportively.</li> </ul>				
Section \$	5: Fire-fighting measure	S				
	able extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical				
Uns med	uitable extinguishing ia	: None known.				
	cific hazards during fire-	: 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.				
Haza ucts	ardous combustion prod-	Carbon oxides Nitrogen oxides (NOx)				
Spec ods	cific extinguishing meth-	<ul> <li>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</li> <li>Use water spray to cool unopened containers.</li> <li>Remove undamaged containers from fire area if it is safe to c so.</li> <li>Evacuate area.</li> </ul>				
	cial protective equipment refighters	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.				
Section	6: Accidental release me	asures				
tive	onal precautions, protec- equipment and emer- cy procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro tective equipment recommendations (see section 8).				
Envi	ronmental precautions	<ul> <li>Avoid release to the environment.</li> <li>Prevent further leakage or spillage if safe to do so.</li> <li>Retain and dispose of contaminated wash water.</li> <li>Local authorities should be advised if significant spillages cannot be contained.</li> </ul>				
	nods and materials for ainment and cleaning up	Sweep up or vacuum up spillage and collect in suitable con- tainer 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 surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis-				



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		employed in the mine which reg Sections 13 an	aterial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.
Section 7	: Handling and storage	9	
Tech	nical measures	causing an exp Provide adequa	/ may accumulate and ignite suspended dust losion. ate precautions, such as electrical grounding r inert atmospheres.
	I/Total ventilation be on safe handling	<ul> <li>Use only with a</li> <li>Do not breathe Do not swallow Avoid contact v Avoid prolonge Wash skin thor Handle in acco practice, based sessment Minimize dust g Keep container Keep away fror Take precautio Do not eat, drin</li> </ul>	dequate ventilation. dust.
Hygie	ene measures	: If exposure to o flushing system place. When using do Wash contamin The effective of engineering con appropriate deg	chemical is likely during typical use, provide eye as and safety showers close to the working not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the rative controls.
	litions for safe storage	: Keep in proper Store in accord	ly labelled containers. ance with the particular national regulations.
Mate	rials to avoid	: Do not store wi Strong oxidizing	th the following product types: g agents

# Section 8: Exposure controls/personal protection

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Propentofylline	55242-55-2	TWA	1000 µg/m3 (	Internal



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			OEB 1)	
Starch	9005-25-8	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Talc	14807-96-6	WES-TWA (Respirable dust)	2 mg/m3	NZ OEL
		TWA (Res- pirable par- ticulate mat- ter)	2 mg/m3	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 equipm	ent	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type Hand protection	•	Particulates type
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.

## Section 9: Physical and chemical properties

Appearance	:	tablet, powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	Not applicable
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable

# SAFETY DATA SHEET



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Evapor	ation rate	:	Not applicable	
Flamm	Flammability (solid, gas)			stible dust concentrations in air during pro g or other means.
Flamm	ability (liquids)	:	Not applicable	
	explosion limit / Upper ability limit	:	No data available	9
	explosion limit / Lower ability limit	:	No data available	9
Vapour	pressure	:	Not applicable	
Relativ	e vapour density	:	Not applicable	
Relativ	e density	:	No data available	9
Density	/	:	No data available	9
Solubili Wat	ity(ies) ter solubility	:	No data available	9
Solu	ubility in other solvents	:	No data available	9
Partitio octanol	n coefficient: n-	:	Not applicable	
	nition temperature	:	No data available	9
Decom	position temperature	:	No data available	9
Viscosi Visc	ty cosity, kinematic	:	Not applicable	
Explosi	ive properties	:	Not explosive	
Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
Molecu	ılar weight	:	Not applicable	
Particle Particle	e characteristics e size	:	No data available	9

## Section 10: Stability and reactivity

Reactivity Chemical stability	Not classified as a reactivity hazard. Stable under normal conditions.
Possibility of hazardous reac- tions	



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			Can react with	strong oxidizing agents.
Cond	itions to avoid	:	Heat, flames a Avoid dust for	
	npatible materials rdous decomposition lcts	:	Oxidizing ager No hazardous	nts decomposition products are known.
ection 1	1: Toxicological infor	matio	on	
Expo	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity ful if swallowed.			
Prod			A	
Acute	e oral toxicity	:	Method: Calcul	stimate: 1,880 mg/kg ation method
<u>Com</u>	oonents:			
-	entofylline: e oral toxicity	:	LD50 (Rat): 94 Symptoms: Bre	0 mg/kg athing difficulties, Convulsions, Lachrymation
			LD50 (Mouse):	780 mg/kg
			LD50 (Rabbit):	405 mg/kg
Starc	h:			
Acute	oral toxicity	:	LD50 (Rat): > 5	5,000 mg/kg
Acute	e dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg
Talc:				
Acute	e oral toxicity	:	LD50 (Rat): > 5 Remarks: Base	5,000 mg/kg ed on data from similar materials
-	corrosion/irritation lassified based on avai	lable	information.	
<u>Com</u>	oonents:			
Talc:			Dabbit	
Speci Resu		:	Rabbit No skin irritatio	n



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## 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 sensitisation

#### Skin sensitisation

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### **Components:**

#### Starch:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

#### Talc:

Exposure routes	:	Skin contact
Species	:	Humans
Result	:	negative

#### **Chronic toxicity**

## Germ cell mutagenicity

Not classified based on available information.

## Components:

## Starch:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
<b>Talc:</b> Genotoxicity in vitro	: Test Type: DNA damage and repair, unscheduled DNA syn
	thesis in mammalian cells (in vitro)

Result: negative



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Geno	otoxicity in vivo	:	Test Type: Chro Species: Rat Application Rou Result: negative	
Not c	inogenicity classified based on ava	ailable	information.	
	ponents:			
	ies cation Route sure time	:	Mouse inhalation (dust 2 Years negative	/mist/fume)
•	oductive toxicity	ailable	information.	
<u>Com</u>	ponents:			
-	entofylline: ts on foetal develop-	:	Test Type: Deve Species: Mouse Application Rou Developmental Result: No adve	te: Ingestion Toxicity: NOAEL: 500 mg/kg body weight
			Test Type: Deve Species: Rabbit Application Rou Developmental Result: No terat	te: Ingestion Toxicity: NOAEL: 150 mg/kg body weight
Talc: Effec ment	ts on foetal develop-	:	Test Type: Emb Species: Rat Application Rou Result: negative	
	<b>T - single exposure</b> classified based on ava	ailable	information.	
May	T - repeated exposur cause damage to orga ponents:		ough prolonged o	or repeated exposure if swallowed.
Prop	entofylline:			
Expo	sure routes ssment	:	Oral May aguag dam	age to organs through prolonged or repeate



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Rei	narks	:	exposure. Based on humar	experience.
Re	peated dose toxicity			
Co	mponents:			
Spe NO App Exp	<b>rch:</b> ecies AEL plication Route posure time thod	::	Rat >= 2,000 mg/kg Skin contact 28 Days OECD Test Guid	eline 410
Not	<b>biration toxicity</b> classified based on availa			
-	perience with human exp	osı	lre	
	mponents:			
	pentofylline: estion	:		ungs Cardiovascular Gastro-intestinal system rointestinal discomfort, Nausea Iervous system
Section	12: Ecological information	on		
Eco	otoxicity			
Co	mponents:			
Pro	pentofylline:			
	otoxicology Assessment ite aquatic toxicity	:	Toxic effects can	not be excluded
Chi	onic aquatic toxicity	:	Toxic effects can	not be excluded
<b>Tal</b> To>	<b>c:</b> ticity to fish	:	LC50 (Brachydar Exposure time: 2	nio rerio (zebrafish)): > 100,000 mg/l 4 h
	sistence and degradabili	ity		



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cumulative potentia	I		
oonents:			
entofylline: on coefficient: n- ol/water	: log Pow: 1.540		
l <b>ity in soil</b> Ita available			
adverse effects ata available			
	06.07.2024 cumulative potentia ponents: entofylline: on coefficient: n- ol/water ity in soil ta available adverse effects	06.07.2024       2929966-00018         cumulative potential	06.07.2024       2929966-00018       Date of first issue: 25.06.2018         cumulative potential

Disposal r	nethods
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•		
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 han-
		dling site for recycling or disposal.
		If not otherwise specified: Dispose of as unused product.

### Section 14: Transport information

## International Regulations

### UNRTDG

UN number Proper shipping name Class Subsidiary risk Packing group Labels Environmentally hazardous	: : : : : : : : : : : : : : : : : : : :	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IMDG-Code UN number Proper shipping name Class Subsidiary risk	: : :	Not applicable Not applicable Not applicable Not applicable



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Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable for product as supplied.

#### National Regulations

NZS 5433	
UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Hazchem Code	: Not applicable

#### Special precautions for user

Not applicable

#### Section 15: Regulatory information

#### Safety, health and environmental regulations/legislation specific for the substance or mixture

### HSNO Approval Number

HSR100757 Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2020

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

DSL	:	not determined
AICS	:	not determined
IECSC	:	not determined

## Section 16: Other information

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Further information	



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compi	Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/				
Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.					
Date	ormat	: c	dd.mm.yyyy		
Full to	Full text of other abbreviations				
ACGI NZ OI		: N		eshold Limit Values (TLV) orkplace Exposure Standards for Atmospher-	
	H / TWA EL / WES-TWA		3-hour, time-weig Workplace Expos	hted average ure Standard - Time Weighted average	

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; KECI - 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; TECI - 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

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 mate-





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rial 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.

NZ / EN