

SAFETY DATA SHEET



Droncit tablets H 50 mg

Version 1.0 Revision Date: 18.06.2020 SDS Number: 122000000910 Date of last issue: -
Date of first issue: 18.06.2020

Section 1: Identification

1.1 Product identifier

Droncit tablets H 50 mg

ACVM number : A002919

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

Use of the Substance/Mixture : Veterinary medicine

1.3 Details of the supplier of the safety data sheet

Company

Elanco New Zealand
88 Shortland Street
1010 AUCKLAND
NEW ZEALAND
+64 0800 352 626
elanco_sds@elancoah.com

1.4 Emergency telephone number

In case of emergency: CHEMTREC International: +1 703-527-3887 (24 hours)
or +64-98010034 (local)

Section 2: Hazard identification

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Praziquantel	55268-74-1	>= 1 -< 10

Section 4: First-aid measures

General advice : You should call the National Poisons Centre if you feel that

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you may have been harmed or irritated by this product. The number is 0800 764 766 (0800 POISON) (24hr emergency service).

- If inhaled : Remove to fresh air.
If symptoms persist, call a physician.
 - In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
If skin reactions occur, contact a physician.
 - In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 - If swallowed : If swallowed, seek medical advice immediately and show this container or label.
 - Most important symptoms and effects, both acute and delayed : No information available.
 - Notes to physician : No information available.
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Section 5: Fire-fighting measures

- Suitable extinguishing media : Any
 - Specific hazards during fire-fighting : Fire may cause evolution of:
Nitrogen oxides (NO_x)
Carbon oxides
 - Specific extinguishing methods : Prevent fire extinguishing water from contaminating surface water or the ground water system.
 - Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
-

Section 6: Accidental release measures

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
 - Environmental precautions : Do not flush into surface water or sanitary sewer system.
 - Methods and materials for containment and cleaning up : Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).
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Section 7: Handling and storage

- Advice on protection against fire and explosion : No special protective measures against fire required.

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- Advice on safe handling : No special precautions required.
- Hygiene measures : Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!
- Conditions for safe storage : For storage suitable stores with adequate product-reception volume must be used.
During handling local official regulations must be observed in order to avert impairment of water by the product.

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA	10 mg/m ³	ACGIH
Starch	9005-25-8	WES-TWA	10 mg/m ³	NZ OEL
		WES-TWA	10 mg/m ³	NZ OEL
		TWA	10 mg/m ³	ACGIH
		TWA	10 mg/m ³	ACGIH

Personal protective equipment

- Respiratory protection : No personal respiratory protective equipment normally required.
Breathing apparatus only if aerosol or dust is formed.
Effective dust mask
- Hand protection
Material : Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear
- Remarks : Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.
- Eye protection : Safety glasses
- Protective measures : No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.
Wear suitable protective equipment.
The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.

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Section 9: Physical and chemical properties

Appearance	:	solid
Colour	:	white
Vapour pressure	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Oxidizing properties	:	No data available
Minimum ignition energy	:	No data available

Section 10: Stability and reactivity

Reactivity	:	No data available
Chemical stability	:	No data available
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	Nitrogen oxides (NOx) Carbon oxides

Section 11: Toxicological information

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate (ATE): > 5.000 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate (ATE): > 5.000 mg/kg Method: Calculation method

Components:

Praziquantel:

Acute oral toxicity	:	LD50 (Rat): 2.840 mg/kg
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Serious eye damage/eye irritation

Components:

Praziquantel:

Result : May irritate eyes.

Chronic toxicity

Germ cell mutagenicity

Components:

Praziquantel:

Genotoxicity in vitro : Test Type: Ames test
Result: No indication of mutagenic effects.

Carcinogenicity

Components:

Praziquantel:

Result : Animal testing did not show any carcinogenic effects.

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Components:

Praziquantel:

Reproductive toxicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

STOT - single exposure

Components:

Praziquantel:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Components:

Praziquantel:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

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Further information

Components:

Praziquantel:

Pharmaceutic effects

Remarks : Anthelmintics

Remarks : Ingestion of large quantities:
Drowsiness
Difficulty in breathing
Ataxia (uncontrolled movements)
Tiredness

Section 12: Ecological information

Ecotoxicity

Components:

Praziquantel:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 35 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EbC50 (Desmodesmus subspicatus (green algae)): 140 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test

ErC50 (Desmodesmus subspicatus (green algae)): 77 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test

NOEbC (Desmodesmus subspicatus (green algae)): 25 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test

NOErC (Desmodesmus subspicatus (green algae)): 25 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test

Toxicity to microorganisms : EC50 (Activated sludge micro-organism): > 1.000 mg/l
Exposure time: 3 h
Method: OECD 209

Ecotoxicology Assessment

Acute aquatic toxicity : Harmful to aquatic life.

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

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Persistence and degradability

Components:

Praziquantel:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: 0 %

Chemical Oxygen Demand (COD) : 2.340 mg/g
Method: DIN 38414

Bioaccumulative potential

Components:

Praziquantel:

Partition coefficient: n-octanol/water : log Pow: 2,012

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

Section 13: Disposal considerations

Disposal methods

Waste from residues : Dispose of as hazardous waste in compliance with local and national regulations.

Contaminated packaging : Contaminated, empty containers are to be treated in the same way as the contents.

Section 14: Transport information

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.

Section 15: Regulatory information

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

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HSNO Approval Number

Not applicable

HSW Controls

Approved handler certificate not required.

HSNO tracking not required.

Refer to EPA user guide to the HSNO control regulations for further information.

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

Stockholm Convention (Persistent Organic Pollutants) : Not applicable

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

NZIoC : On the inventory, or in compliance with the inventory

Section 16: Other information

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AICS - Australian Inventory of Chemical Substances; 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

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es; (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; 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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