

SAFETY DATA SHEET



Drontal Allwormer for Cats

Version 1.0 Revision Date: 19.06.2020 SDS Number: 122000001469 Date of last issue: -
Date of first issue: 19.06.2020

Section 1: Identification

1.1 Product identifier

Drontal Allwormer for Cats

ACVM number : A008215, A007042

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

Use of the Sub-stance/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

Respiratory sensitisation : 6.5A

Skin sensitisation : 6.5B

Aquatic toxicity (Acute or Chronic) : 9.1C

GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H412 Harmful to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P285 In case of inadequate ventilation wear respiratory protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P321 Specific treatment (see supplemental first aid instructions on this label).
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.
P363 Wash contaminated clothing before reuse.

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

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)
Pyrantel pamoate	22204-24-6	>= 50 -< 70
Praziquantel	55268-74-1	>= 1 -< 10

Section 4: First-aid measures

General advice : Take off all contaminated clothing immediately.

You should call the National Poisons Centre if you feel that 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.

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- 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.
-

Section 5: Fire-fighting measures

- Suitable extinguishing media : Any
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire-fighting : Fire may cause evolution of:
Hydrogen cyanide (hydrocyanic acid)
Sulphur oxides
Nitrogen oxides (NOx)
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. Use personal protective equipment.
-

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).
-

Section 7: Handling and storage

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Industrial uses:
Avoid dust formation.
Use with local exhaust ventilation.
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Avoid contact with skin, eyes and clothing.

- 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
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
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA	10 mg/m ³	ACGIH
Hydroxypropyl methylcellulose	9004-65-3	SUP	10 mg/m ³	OEL

Personal protective equipment

- Respiratory protection : Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)
- 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.
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.
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.

Section 9: Physical and chemical properties

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Appearance : tablet
Colour : yellowish
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Explosive properties : No statements available.
Oxidizing properties : No data available
Impact sensitivity : 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 : Exposure to moisture
Incompatible materials : No data available
Hazardous decomposition products : Hydrogen cyanide (hydrocyanic acid)
Sulphur oxides
Nitrogen oxides (NO_x)
Carbon oxides

Section 11: Toxicological information

Acute toxicity

Product:

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

Components:

Pyrantel pamoate:

Acute oral toxicity : LD50 (Rat): > 24.000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Praziquantel:

Acute oral toxicity : LD50 (Rat): 2.840 mg/kg

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Skin corrosion/irritation

Product:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Product:

Species : Rabbit
Result : No eye irritation

Components:

Pyrantel pamoate:

Result : May irritate eyes.

Praziquantel:

Result : May irritate eyes.

Respiratory or skin sensitisation

Components:

Pyrantel pamoate:

Test Type : Skin sensitisation
Result : May cause sensitisation by skin contact.
: Respiratory sensitisation
: May cause sensitisation by inhalation.

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.

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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.

Further information

Components:

Pyrantel pamoate:

Pharmaceutic effects
Remarks : Anthelmintics

Praziquantel:

Pharmaceutic effects
Remarks : Anthelmintics

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

Section 12: Ecological information

Ecotoxicity

Components:

Pyrantel pamoate:

Toxicity to fish : LC0 (Danio rerio (zebra fish)): > 60,6 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 12,68 mg/l
Exposure time: 48 h

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.

Persistence and degradability

Components:

Pyrantel pamoate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 2 %
Exposure time: 28 d

Praziquantel:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: 0 %

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

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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

No statements available.

HSW Controls

Certified handler certificate not required.

HSW tracking not required.

Refer to WORKSAFE user guide to the HSW regulations for further information.

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

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Stockholm Convention (Persistent Organic Pollutants) : Not applicable

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

NZIoC : Not 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
OEL : OEL (Occupational exposure limit):
ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average
OEL / SUP : Suppliers - limit

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; (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

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 given is designed only as a guid-

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