

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Drontal Allwormer Chewable for Dogs

HSNO Approval Number : HSR007764

ACVM number : A009856

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

Bayer New Zealand Limited
3 Argus Place
0627 HILLCREST, AUCKLAND, NEW ZEALAND
NEW ZEALAND
Tel.: 0800 652 488
Fax: 0800 229 838
Mail: bhc-md-oeko@bayer.com

1.4 Emergency telephone number

In case of emergency: 0800 734 607 IXOM SH&E Shared services (24hr)

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

6.8: Toxic to Reproduction : Category B

6.9: Specific Target Organ Toxicity : Category B

9.1: Aquatic toxicity (Acute or Chronic) : Category B

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361 Suspected of damaging fertility or the unborn child.
H371 May cause damage to organs if swallowed.
H411 Toxic to aquatic life with long lasting effects.

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
Response:
P391 Collect spillage.
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

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Febantel	58306-30-2	>= 10 -< 20
Pyrantel pamoate	22204-24-6	>= 2,5 -< 10
Sodium chloride	7647-14-5	>= 1 -< 10
Praziquantel	55268-74-1	>= 1 -< 10
Croscarmellose sodium	74811-65-7	>= 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.
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.
No information available.

Notes to physician : No information available.

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Any
- Specific hazards during fire-fighting : Fire may cause evolution of:
Carbon monoxide (CO)
Carbon dioxide (CO₂)
- 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.
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
Glycerol	56-81-5	WES-TWA (Mist)	10 mg/m ³	NZ OEL

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

Starch	9005-25-8	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Sucrose / Sugar	57-50-1	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH

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

Appearance : tablet
Colour : brown
Odour : characteristic
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

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

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 : Carbon monoxide (CO)
Carbon dioxide (CO₂)

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:

Febantel:

Acute oral toxicity : LD50 (Rat, female): 1.760 mg/kg

Acute inhalation toxicity : LC0 (Rat): > 2 mg/l
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The component/mixture is minimally toxic after single contact with skin.

Acute toxicity (other routes of administration) : LD50 (Mouse): > 10.000 mg/kg
Application Route: Subcutaneous

Pyrantel pamoate:

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

Sodium chloride:

Acute oral toxicity : LD50 (Rat): > 3.980 mg/kg
Assessment: The component/mixture is minimally toxic after single ingestion.

Acute inhalation toxicity : LC50 (Rat, male): > 10,5 mg/l
Exposure time: 4 h

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

Test atmosphere: dust/mist/aerosol
Method: Expert judgement
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 (Rabbit): > 10.000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Praziquantel:

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

Croscarmellose sodium:

Acute oral toxicity : LD50 (Rat): > 5.050 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The component/mixture is minimally toxic after single contact with skin.

Skin corrosion/irritation

Components:

Febantel:

Species: Rabbit
Result: No skin irritation

Sodium chloride:

Species: Rabbit
Method: OECD 404
Result: No skin irritation

Croscarmellose sodium:

Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation

Components:

Febantel:

Species: Rabbit
Result: No eye irritation

Pyrantel pamoate:

Result: May irritate eyes.

Sodium chloride:

Species: Rabbit
Result: No eye irritation

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

Method: OECD 405
Remarks: Mechanical irritation of the eyes is possible.

Praziquantel:

Result: May irritate eyes.

Croscarmellose sodium:

Species: Rabbit
Remarks: slight irritation

Respiratory or skin sensitisation

Components:

Pyrantel pamoate:

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

Test Type: Respiratory sensitisation
Result: May cause sensitisation by inhalation.

Sodium chloride:

Test Type: Skin sensitisation
Species: Mouse
Result: Did not cause sensitisation on laboratory animals.

Croscarmellose sodium:

Test Type: Skin sensitisation
Species: Guinea pig
Result: Did not cause sensitisation on laboratory animals.

Chronic toxicity

Germ cell mutagenicity

Components:

Sodium chloride:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD 471
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vivo
Species: Rat (female)
Cell type: Bone marrow
Application Route: Intraperitoneal
Method: OECD 475
Result: positive
Remarks: The available study results do not lead to a GHS classification

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

Praziquantel:

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

Croscarmellose sodium:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Carcinogenicity

Components:

Sodium chloride:

Species: Rat, (male)
Application Route: Oral
Frequency of Treatment: once daily
Method: OECD 453
Result: Animal testing did not show any carcinogenic effects.

Praziquantel:

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.

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

Repeated dose toxicity

Components:

Sodium chloride:

Species: Rat, male
LOAEL: 2.533 mg/kg
Application Route: Oral
Exposure time: 24 month
Number of exposures: Continuous exposure via feed.
Method: OECD 453

Further information

Components:

Febantel:

Pharmaceutic effects
Remarks: Anthelmintics

Pyrantel pamoate:

Pharmaceutic effects
Remarks: Anthelmintics

Sodium chloride:

Remarks: If swallowed
After absorption of large quantities
Nausea
Vomiting

Praziquantel:

Pharmaceutic effects
Remarks: Anthelmintics

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Febantel:

Toxicity to fish : LC0 (Danio rerio (zebra fish)): > 10.000 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1,8 mg/l

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

aquatic invertebrates Exposure time: 48 h

Toxicity to algae : ErC50 (Desmodesmus subspicatus (green algae)): > 0,43 mg/l
Exposure time: 72 h
Method: OECD 201

EbC50 (Desmodesmus subspicatus (green algae)): > 0,43 mg/l
Exposure time: 72 h
Method: OECD 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50 (activated sludge micro-organism): > 10.000 mg/l
Method: ISO 8192

Pyrantel pamoate:

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

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

Sodium chloride:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 7.650 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity
Method: OECD 203

LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l
Exposure time: 96 h
Test Type: flow-through test

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d
Method: OECD 210

Lowest Observed Effect Concentration (Pimephales promelas (fathead minnow)): 352 mg/l
Exposure time: 33 d
Method: OECD 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d
Test Type: Reproductive toxicity
Method: OECD 211

Lowest Observed Effect Concentration (Daphnia pulex (Water flea)): 441 mg/l
Exposure time: 21 d
Test Type: Reproductive toxicity

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

Method: OECD 211

- Toxicity to microorganisms : EC10 (activated sludge micro-organism): 35.000 mg/l
- Toxicity to soil dwelling organisms : Test Type: laboratory study
LC50 (Eisenia fetida (earthworms)): > 3.507 mg/kg
Exposure time: 70 d
- Toxicity to terrestrial organisms : LD50 (Passer domesticus (house sparrow)): 8.000 mg/kg
Exposure time: 72 d

Ecotoxicology Assessment

Acute aquatic toxicity : slightly water endangering

Praziquantel:

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

Sodium chloride:

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Praziquantel:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: 0 %

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

Bioaccumulative potential

Components:

Febantel:

Partition coefficient: n-octanol/water : log Pow: 3,2

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.

Components:

Sodium chloride:

Results of PBT and vPvB assessment : Remarks: Not applicable

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

International Regulations

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version 1.0 Revision Date: 15.01.2019 SDS Number: 122000015887 Date of last issue: -
Date of first issue: 15.01.2019

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (FEBANTEL)
Class : 9
Packing group : III
Labels : 9
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (FEBANTEL)
Class : 9
Packing group : III
Labels : 9
Marine pollutant : no

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

Not applicable for product as supplied.

National Regulations

SECTION 15. REGULATORY INFORMATION

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

HSNO Approval Number

HSR007764

HSNO Controls

Approved handler certificate not required.

HSNO tracking not required.

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

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

Full text of other abbreviations

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; CPR - Controlled Products Regulations; 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% re-

SAFETY DATA SHEET

Drontal Allwormer Chewable for Dogs



Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.01.2019	122000015887	Date of first issue: 15.01.2019

sponse; 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

Date format : dd.mm.yyyy

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

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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

NZ / EN