

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

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### Section 1: Identification

#### 1.1 Product identifier

Drontal Allwormer for Large Dogs

HSNO Approval Number : HSR001939

ACVM number : A007451

#### 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)

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### Section 2: Hazard identification

#### GHS Classification

Toxic to Reproduction : 6.8B

Specific Target Organ Toxicity : 6.9B

#### GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H361 Suspected of damaging fertility or the unborn child.  
H373 May cause damage to organs through prolonged or repeated exposure if swallowed.

Precautionary statements : P103 Read label before use.

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

---

### Prevention:

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
P281 Use personal protective equipment as required.

### Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P314 Get medical advice/ attention if you feel unwell.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents/container to an approved facility in accordance with local, regional, national and international regulations.

### Other hazards which do not result in classification

None known.

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## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Febantel	58306-30-2	>= 30 -< 50
Pyrantel pamoate	22204-24-6	>= 20 -< 25
Praziquantel	55268-74-1	>= 1 -< 10

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## Section 4: First-aid measures

General advice : Take off contaminated clothing and shoes immediately.

If inhaled : Remove to fresh air.  
If symptoms persist, call a physician.

In case of skin contact : Wash off immediately with soap and plenty of water.  
If symptoms persist, call 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 : No information available.

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# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	18.06.2020	122000000607	Date of first issue: 18.06.2020

---

delayed

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : No information available.

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### 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)  
Carbon oxides  
Sulphur oxides  
Nitrogen oxides (NOx)

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.

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### 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.

Advice on safe handling : Avoid dust formation.  
Use with local exhaust ventilation.  
Avoid contact with skin, eyes and clothing.

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.

Recommended storage temperature : 15 - 30 °C

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# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
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### 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 <sup>3</sup>	NZ OEL
		WES-TWA	10 mg/m <sup>3</sup>	NZ OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA	10 mg/m <sup>3</sup>	ACGIH
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA	10 mg/m <sup>3</sup>	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.
- 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.

### Section 9: Physical and chemical properties

- Appearance : tablet
- Colour : yellowish
- Odour : slight, musty
- Odour Threshold : No data available
- pH : No data available
- Melting point / range : No data available
- Boiling point/boiling range : No data available

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	18.06.2020	122000000607	Date of first issue: 18.06.2020

---

Flash point	:	No data available
Evaporation rate	:	No data available
Burning rate	:	No data available
Self-ignition	:	No data available
Burning number	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	No data available
Solubility(ies)		
Water solubility	:	200 g/l suspendable (15 °C)
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Impact sensitivity	:	No data available
Minimum ignition energy	:	No data available

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### Section 10: Stability and reactivity

Reactivity	:	No data available
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# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

---

Chemical stability : No data available

Possibility of hazardous reactions : No data available

Conditions to avoid : Heat  
Exposure to moisture

Incompatible materials : Oxidizing agents

Hazardous decomposition products : Hydrogen cyanide (hydrocyanic acid)  
Carbon oxides  
Sulphur oxides  
Nitrogen oxides (NOx)

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### Section 11: Toxicological information

#### Acute toxicity

##### Product:

Acute oral toxicity : Acute toxicity estimate (ATE): > 2.000 mg/kg  
Method: Calculation method  
Assessment: No adverse effect has been observed in acute toxicity tests.  
Remarks: Calculated for GHS Classification and Labelling.

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

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.

##### **Praziquantel:**

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

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

---

### Skin corrosion/irritation

#### Components:

##### Febantel:

Species : Rabbit  
Result : No skin irritation

### Serious eye damage/eye irritation

#### Components:

##### Febantel:

Species : Rabbit  
Result : No eye irritation

##### 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.

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

---

### Reproductive toxicity

#### Components:

##### **Febantel:**

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.  
Clear evidence of adverse effects on development, based on animal experiments.

##### **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

#### Product:

Remarks : Dogs treated with elevated levels (6 consecutive days with 3 times the labeled dosage rate) of the combination of febantel and praziquantel in early pregnancy demonstrated an increased incidence of abortion and fetal abnormalities. The effects of Drontal® Plus on pregnant animals have not been determined.

#### Components:

##### **Febantel:**

Pharmaceutical effects  
Remarks : Anthelmintics

##### **Pyrantel pamoate:**

Pharmaceutical effects  
Remarks : Anthelmintics



# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

---

### **Praziquantel:**

Pharmaceutic effects

Remarks : Anthelmintics

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

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## 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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,8 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : 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

#### **Praziquantel:**

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

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

---

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

### Bioaccumulative potential

#### Components:

##### **Febantel:**

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

##### **Praziquantel:**

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

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

---

### Mobility in soil

No data available

### Other adverse effects

#### Product:

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

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## 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.

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## Section 14: Transport information

### 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  
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 : yes

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

Not applicable for product as supplied.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version 1.0      Revision Date: 18.06.2020      SDS Number: 122000000607      Date of last issue: -  
Date of first issue: 18.06.2020

---

### Section 15: Regulatory information

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

##### HSNO Approval Number

HSR001939

##### 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

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### 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

# SAFETY DATA SHEET



## Drontal Allwormer for Large Dogs

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	18.06.2020	122000000607	Date of first issue: 18.06.2020

---

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 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.

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