

SAFETY DATA SHEETS

This SDS packet was issued with item:

078950719

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078950718 078950720 078950768 078950769

SAFETY DATA SHEET



Drontal Plus Taste Tabs

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06/23/2020	122000007082	Date of first issue: 23.06.2020

SECTION 1. IDENTIFICATION

Product information

Product Name : Drontal Plus Taste Tabs
SDS Number : 122000007082

Use : veterinary medicine

Company

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
USA
+1-877-Elanco1(+1-877-3526261)
elanco_sds@elanco.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Respiratory sensitisation : Category 1
Skin sensitisation : Category 1
Reproductive toxicity : Category 1B

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.
H360D May damage the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P285 In case of inadequate ventilation wear respiratory protec-

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tion.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Febantel	58306-30-2	15
Pyrantel pamoate	22204-24-6	8,71
Praziquantel	55268-74-1	3

SECTION 4. FIRST AID MEASURES

General advice : No hazards which require special first aid measures.

If inhaled : Not an expected entry route.

In case of skin contact : No hazards which require special first aid measures.

In case of eye contact : Flush eyes with water as a precaution.

If swallowed : In case of accidental ingestion, contact your regional poison center or physician immediately.

Most important symptoms and effects, both acute and delayed : No information available.

Notes to physician : No information available.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Any

Unsuitable extinguishing media : none

Specific hazards during fire-fighting : Fire may cause evolution of:
Carbon monoxide (CO)
Carbon dioxide (CO₂)

Further information : 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.

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.

Recommended storage temperature : < 77 °F / < 25 °C

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
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Silicon dioxide (amorphous)	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m ³ / %SiO ₂ (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m ³ /	OSHA Z-3

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			%SiO ₂ (Silica)	
		TWA	6 mg/m ³ (Silica)	NIOSH REL
		TWA	6 mg/m ³ (Silica)	NIOSH REL
Stearic acid	57-11-4	TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH

Personal protective equipment

Respiratory protection : Recommended Filter type:
HEPA
None required for consumer use of this product.

Hand protection
Material : Chemically resistant gloves.

Remarks : None required for consumer use of this product.

Eye protection : Safety glasses
None required for consumer use of this product.

Protective measures : Wear suitable protective equipment.
Please consult label for end-user requirements.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet
Colour : brown
Odour : slight, musty
Melting point / range : No data available

Boiling point/boiling range : No data available

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

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Chemical stability	:	No data available
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	No data available
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	Carbon monoxide (CO) Carbon dioxide (CO ₂)

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
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.
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Praziquantel:

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

Components:

Febantel:

Species	:	Rabbit
Result	:	No skin irritation

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Serious eye damage/eye irritation**Components:****Febantel:**

Species	:	Rabbit
Result	:	No eye irritation

Pyrantel pamoate:

Result	:	May irritate eyes.
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Praziquantel:

Result	:	May irritate eyes.
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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.

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.
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Carcinogenicity - Assessment	:	Animal testing did not show any carcinogenic effects.
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IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
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NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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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**Components:****Febantel:**

Pharmaceutic effects
Remarks : Anthelmintics

Pyrantel pamoate:

Pharmaceutic effects
Remarks : Anthelmintics

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 |
| 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 |
| 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 |

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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

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 : If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic.

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However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

SECTION 14. TRANSPORT INFORMATION

International Regulations

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.

National Regulations

49 CFR

Not regulated as a dangerous good

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.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitisation

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Reproductive toxicity

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

Cellulose	9004-34-6
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Pennsylvania Right To Know

Cellulose	9004-34-6
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New York City Hazardous Substances

No components listed on the New York City Hazardous Substances List

California Permissible Exposure Limits for Chemical Contaminants

Silicon dioxide (amorphous)	112945-52-5
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International Regulations

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:

TSCA : Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

Health - 2	Flammability - 1	Instability - 0	Others -
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HMIS® IV:

Health - 2	Flammability - 1	Instability - 0	Others -
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Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA P0	: USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

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OSHA Z-3	:	its for Air Contaminants USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

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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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