

SAFETY DATA SHEETS

This SDS packet was issued with item:

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N/A

SAFETY DATA SHEET



Droncit Injectable for Dogs & Cats

Version 1.0 Revision Date: 06/24/2020 SDS Number: 122000001124 Date of last issue: -
Date of first issue: 24.06.2020

SECTION 1. IDENTIFICATION

Product information

Product Name : Droncit Injectable for Dogs & Cats
Synonyms : Droncit (praziquantel) Injectable for Dogs & Cats
SDS Number : 122000001124

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

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl alcohol	100-51-6	7,19
Praziquantel	55268-74-1	5,45

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 : If skin reactions occur, contact a physician.

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.

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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- Unsuitable extinguishing media : High volume water jet
- 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
No special precautions required.
- Methods and materials for containment and cleaning up : Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Keep this and all drugs out of the reach of children.
Store in a dry place away from excessive heat.
Containers should be kept tightly closed to prevent contamination.
Use normal precautions for storage of a drug.
Avoid contact with skin, eyes and clothing.
- Recommended storage temperature : 86 °F / 30 °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
Propane-1,2-diol	57-55-6	TWA	10 mg/m ³	US WEEL
		TWA	10 mg/m ³	US WEEL
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
		TWA	10 ppm	US WEEL
Propane-1,2-diol	57-55-6	TWA	10 mg/m ³	US WEEL
		TWA	10 mg/m ³	US WEEL
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
		TWA	10 ppm	US WEEL

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Personal protective equipment

Respiratory protection	:	Recommended Filter type: Organic vapor with prefilter 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	:	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. Please consult label for end-user requirements.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	colorless to tinted
Odour	:	sweet, fruity
Odour Threshold	:	No data available
pH	:	No data available
Melting point / range	:	No data available
Boiling point/boiling range	:	ca. 212 °F / 100 °C (1.013 hPa)
Flash point	:	209,3 °F / 98,5 °C
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
Density	:	ca. 1,0430 g/cm ³ (68 °F / 20 °C)
Bulk density	:	No data available

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Solubility(ies)	
Water solubility	: No data available
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 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	: Do not allow product to come in contact with: Exposure to light. Exposure to air.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known. 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 inhalation toxicity	: Acute toxicity estimate (ATE): 152,99 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Calculation method
Acute dermal toxicity	: Acute toxicity estimate (ATE): > 5.000 mg/kg Method: Calculation method

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Components:**Benzyl alcohol:**

Acute oral toxicity	:	LD50 (Rat, male): 1.620 mg/kg Assessment: The component/mixture is moderately toxic after single ingestion.
Acute inhalation toxicity	:	Assessment: The component/mixture is moderately toxic after short term inhalation.

Praziquantel:

Acute oral toxicity	:	LD50 (Rat): 2.840 mg/kg
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Skin corrosion/irritation**Components:****Benzyl alcohol:**

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

Serious eye damage/eye irritation**Components:****Benzyl alcohol:**

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 7 days
Method	:	OECD 405

Praziquantel:

Result	:	May irritate eyes.
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Respiratory or skin sensitisation**Components:****Benzyl alcohol:**

Species	:	Guinea pig
Method	:	Magnusson and Kligmann maximization test
Result	:	Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity**Components:****Benzyl alcohol:**

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

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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.

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.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

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.

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:****Benzyl alcohol:**

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

Praziquantel:

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

STOT - repeated exposure**Components:****Benzyl alcohol:**

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

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Praziquantel:

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

Repeated dose toxicity**Components:****Benzyl alcohol:**

Species	: Rat
NOAEL	: 400 mg/kg
Exposure time	: 90-day

Further information**Components:****Benzyl alcohol:**

Remarks	: Dermal absorption possible
Remarks	: If inhaled: irritations Shortness of breath Cough
Remarks	: If swallowed Vomiting Nausea Irritation of mucous membranes in the mouth, throat, gullet and gastro-intestinal tract after swallowing.
Remarks	: Systemic toxicity Headache Nausea CNS disorders Ataxia (uncontrolled movements) Unconsciousness cessation of breathing

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:****Benzyl alcohol:**

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 10 mg/l Exposure time: 96 h Test Type: Acute Fish toxicity
Toxicity to microorganisms	:	EC50 (Photobacterium phosphoreum): 71,4 mg/l Exposure time: 0,5 h

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic to aquatic life.
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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:****Benzyl alcohol:**

Biodegradability	:	Result: rapidly biodegradable
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Biodegradation: 92 - 96 %
Exposure time: 28 d
Method: OECD 301 C

Praziquantel:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: 0 %

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

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1,05

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. 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

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.

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National Regulations

49 CFR

Not regulated as a dangerous good

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 : Exempt from SARA Section 311/312
No SARA Hazards

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

Benzyl alcohol	100-51-6
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Pennsylvania Right To Know

Propane-1,2-diol	57-55-6
Benzyl alcohol	100-51-6

New York City Hazardous Substances

No components listed on the New York City Hazardous Substances List

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.

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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

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

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

US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA	:	8-hr TWA

Revision Date : 06/24/2020

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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