

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

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# 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 (CO<sub>2</sub>)
- 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 <sup>3</sup>	US WEEL
		TWA	10 mg/m <sup>3</sup>	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 <sup>3</sup>	US WEEL
		TWA	10 mg/m <sup>3</sup>	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 <sup>3</sup> (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 <sub>2</sub> )

### 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

**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.

**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

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