122000007170

SAFETY DATA SHEET

Drontal

Version 5.0 Revision Date 09/18/2015

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

Product information

Product Name: Drontal SDS Number: 122000007170

Use : veterinary medicine

Company

BAYER HEALTHCARE LLC Animal Health Division 12707 Shawnee Mission Parkway (West 63rd) Shawnee, KS 66216-1846 USA (800) 633-3796

In case of emergency: (800) 422-9874

Chemtrec: (800) 424-9300

BAYER INFORMATION PHONE: (800) 633-3796

INTERNATIONAL: (703) 527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

Colour: yellow Form: tablet Odour: slight, musty.

GHS Classification:

Eye irritation: Category 2Respiratory sensitisation: Category 1Skin sensitization: Category 1Hazardous to the aquatic: Category 3

environment

GHS Label element:

Hazard pictograms

Signal word : Danger

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Hazard statements: H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements: Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

P273 Avoid release to the environment.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P333 + P313 If skin irritation or rash occurs: Get medical advice/

attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON

CENTER or doctor/ physician.

Other hazards which do not result in classification:

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent 69.697%	Components Pyrantel pamoate	CAS-No. 22204-24-6
5 - 10%	Cellulose	9004-34-6
6.061%	Praziquantel	55268-74-1

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately.

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.

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If swallowed: If swallowed, seek medical advice immediately and show this container or label.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Any

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

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for 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).

Additional advice: Avoid dust formation.

Further Accidental

Avoid dust formation.

Release Notes

7. HANDLING AND STORAGE

Handling:

Avoid dust formation. Only handle product with local exhaust ventilation. Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.

Storage:

Storage temperature: < 86 °F (< 30 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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Respiratory protection:

Recommended Filter type: HEPA

None required for consumer use of this product.

Hand protection:

Chemically resistant gloves.

None required for consumer use of this product.

Eye protection:

Safety glasses

None required for consumer use of this product.

Other protective measures:

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form: tablet
Colour: yellow
Odour: slight, musty

Odour Threshold: No applicable information is available Melting point: No applicable information is available Boiling point/boiling range: No applicable information is available Density: No applicable information is available Bulk density: No applicable information is available Vapour pressure: No applicable information is available No applicable information is available Viscosity, dynamic: Viscosity, kinematic: No applicable information is available Flow time: No applicable information is available Surface tension: No applicable information is available Miscibility with water: No applicable information is available Water solubility: No applicable information is available pH: No applicable information is available Relative density: No applicable information is available Partition coefficient: No applicable information is available Solubility(ies): No applicable information is available Flash point: No applicable information is available Flammability (solid, gas): No applicable information is available Ignition temperature: No applicable information is available **Explosion limits:** No applicable information is available

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10. STABILITY AND REACTIVITY

Conditions to avoid: No data available

Materials to avoid: Oxidizing agents

Hazardous reactions: None known.

Thermal decomposition:

No data available

Hazardous decomposition products:

Carbon monoxide (CO), Carbon dioxide (CO2)

Oxidizing properties:

No statements available.

Impact sensitivity:

No data available

11. TOXICOLOGICAL INFORMATION

Other information on toxicity:

Praziquantel

Ingestion of large quantities: Dizziness, Dizziness, Difficulty in breathing, Convulsions, Tiredness

Other information on toxicity:

Praziquantel

Ingestion of large quantities: Dizziness, Dizziness, Difficulty in breathing, Convulsions, Tiredness

Acute oral toxicity:

Pyrantel pamoate

LD50 Rat: > 24,000 mg/kg

The substance or mixture has no acute oral toxicity

Praziquantel

LD50 Rat: 2,840 mg/kg May be harmful if swallowed.

Pyrantel pamoate

LD50 Rat: > 24,000 mg/kg

The substance or mixture has no acute oral toxicity

Cellulose

LD50 Rat: > 5,000 mg/kg

The substance or mixture has no acute oral toxicity

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Praziquantel

LD50 Rat: 2,840 mg/kg May be harmful if swallowed.

Acute inhalation toxicity:

Cellulose

LC50 Rat: > 5.05 mg/l, 4 h May be harmful if inhaled.

Acute dermal toxicity:

Praziquantel

Harmful in contact with skin.

Cellulose

LD50 Rabbit: > 2,000 mg/kg

May be harmful in contact with skin.

Praziquantel

Harmful in contact with skin.

Skin irritation:

Cellulose

Rabbit

Result: No skin irritation

Eye irritation:

Pyrantel pamoate

Result: Causes eye irritation.

Praziquantel

Result: Mild eye irritation

Pyrantel pamoate

Result: Causes eye irritation.

Cellulose Rabbit

Result: No eye irritation

Praziquantel

Result: Mild eye irritation

Sensitisation:

Pyrantel pamoate Skin sensitization

Result: Causes sensitisation.

Respiratory tract sensitization Result: Causes sensitisation.

Pyrantel pamoate Skin sensitization

Result: Causes sensitisation.

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Respiratory tract sensitization Result: Causes sensitisation.

Cellulose

Skin sensitization guinea pig

Result: Did not cause sensitisation on laboratory animals.

Genotoxicity in vitro:

Praziquantel Ames test

Result: negative, No evidence of a gene mutagenic effect.

Cellulose Ames test

Result: negative

Praziquantel

Ames test

Result: negative, No evidence of a gene mutagenic effect.

Genotoxicity in vivo:

Cellulose

Mouse

Result: No indication of mutagenic effects.

Carcinogenicity:

Praziquantel

Result: Animal testing did not show any carcinogenic effects.

Praziquantel

Result: Animal testing did not show any carcinogenic effects.

Reproductive toxicity:

Praziquantel

Result: Animal testing did not show any effects on fertility.

Praziquantel

Result: Animal testing did not show any effects on fertility.

Teratogenicity:

Praziquantel

Result: Did not show teratogenic effects in animal experiments.

Praziquantel

Result: Did not show teratogenic effects in animal experiments.

Pharmaceutic effects:

Pyrantel pamoate

Anthelmintics

Praziquantel

Anthelmintics

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Praziquantel Anthelmintics

Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

STOT - single exposure:

No data available

STOT - repeated exposure:

No data available

12. ECOLOGICAL INFORMATION

General advice:

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Pyrantel pamoate

Acute Fish toxicity: LC0 > 60.6 mg/l

Test species: Danio rerio (zebra fish) Duration of test: 96 h

Praziquantel

Acute Fish toxicity: LC50 17 mg/l

Duration of test: 24 h

Pyrantel pamoate

Acute Fish toxicity: LC0 > 60.6 mg/l

Test species: Danio rerio (zebra fish) Duration of test: 96 h

Cellulose

Acute Fish toxicity: LC50 > 100 mg/l

Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

Praziquantel

Acute Fish toxicity: LC50 17 mg/l

Duration of test: 24 h

Toxicity to daphnia and other aquatic invertebrates:

Pyrantel pamoate EC50 12.68 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

Praziquantel EC0 35 mg/l

EC100 100 mg/l

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Pyrantel pamoate EC50 12.68 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

Cellulose

LC50 > 100 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

Praziquantel EC0 35 mg/l

EC100 100 mg/l

Toxicity to algae:

Praziquantel

Cell multiplication inhibition test EbC50 140 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test ErC50 77 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test NOEbC 25 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test NOErC 25 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cellulose

EC50 > 100 mg/l Duration of test: 96 h

NOEC 12.5 mg/l Duration of test: 96 h

Praziquantel

Cell multiplication inhibition test EbC50 140 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test ErC50 77 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test NOEbC 25 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test NOErC 25 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Toxicity to bacteria:

Praziquantel

EC50 > 1,000 mg/l Duration of test: 3 h

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Praziquantel

EC50 > 1,000 mg/l Duration of test: 3 h

Biodegradability:

Pyrantel pamoate

2 %, 28 d Not readily biodegradable.

Praziquantel

0 %, Not readily biodegradable.

Pyrantel pamoate

2 %, 28 d Not readily biodegradable.

Cellulose

inherently degradable

Praziquantel

0 %, Not readily biodegradable.

13. DISPOSAL CONSIDERATIONS

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)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION

Land transport (CFR)

non-regulated

US Sea transport (IMDG)

non-regulated

US Air transport (ICAO / IATA cargo aircraft only)

non-regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)

non-regulated

15. REGULATORY INFORMATION

Other regulations: No statements available.

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US. Toxic Substances Control Act

This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A) Components

None

SARA Section 311/312 Hazard

Exempt from SARA Section 311/312

Categories

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required Components

None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components

None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists Weight percent Components CAS-No.

5 - 10% Cellulose 9004-34-6

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Not subject to OSHA

16. OTHER INFORMATION

Further information

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.