

SAFETY DATA SHEETS

This SDS packet was issued with item:

078933872

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

078551848 078551855 078551863 078551871 078933870 078933871 078933873



SAFETY DATA SHEET
IVERHART MAX® Soft Chew
(ivermectin/pyrantel pamoate/praziquantel)

1. IDENTIFICATION

| | |
|---|--|
| Product Name | IVERHART MAX® Soft Chew (ivermectin/pyrantel pamoate/praziquantel) |
| Recommended use of the chemical and restrictions on use | |
| Identified uses | Soft chew for worm control in dogs |
| Restrictions on Use | Federal law restricts this drug to use by or on the order of a licensed veterinarian. |
| Company Identification | Virbac AH, Inc. P.O. Box 162059 Fort Worth, Texas 76161 (800) 338-3659 |
| Customer Information Number | |
| Emergency Telephone Number | |
| Chemtrec Number | (800) 424-9300 |
| Other Emergency Number: | Poison Control Center: 1-800-222-1222 (human) HOT LINE NUMBER: 1-800-345-4735 (human and pet) |
| Issue Date | September 30, 2017 |
| Supersedes Date | This is the first issue. |
| <i>Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling</i> | |

2. HAZARDS IDENTIFICATION

Hazard Classification
Acute Hazards to the Aquatic Environment – Category 2 (This classification not adopted by OSHA.)

Label Elements
Hazard Symbols
None

Signal Word: None

Hazard Statements
Toxic to aquatic life.

Precautionary Statements
Prevention
Avoid release to the environment.

Response
None

Storage
None

Disposal
Dispose of contents/container in accordance with local regulation.

Other Hazards
None



2. HAZARDS IDENTIFICATION

Specific Concentration Limits

The values listed below represent the percentages of ingredients of unknown toxicity.

| | |
|---------------------------|-----------|
| Acute oral toxicity | 35 - 45% |
| Acute dermal toxicity | 60 - 70% |
| Acute inhalation toxicity | 90 - 100% |
| Acute aquatic toxicity | 70 - 80% |

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms:

This product is a mixture.

| Component Name | CAS Number | Concentration |
|--------------------------|------------|---------------|
| Pyrantel as pamoate salt | 22204-24-6 | 4 - 6 % |
| Praziquantel | 55268-74-1 | 1 - 3% |
| Ivermectin | 70288-86-7 | <0.01% |

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eyes

Not an expected route of entry. If chew contacts eye, flush thoroughly with water. If pain or irritation persists contact a physician.

Skin

If irritation develops wash skin thoroughly with soap and water. Obtain medical attention if redness or soreness persists.

Ingestion

Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Inhalation

Not applicable

Most important symptoms/effects, acute and delayed

Aside from the information found under Description of necessary first aid measures (above) and Indication of immediate medical attention and special treatment needed, no additional symptoms and effects are anticipated.

Indication of immediate medical attention and special treatment needed

Notes to Physicians

Treat symptomatically.

5. FIRE - FIGHTING MEASURES

Extinguishing Media

Use extinguishing media appropriate for surrounding materials.

Unusual Fire and Explosion Hazards

Can release hazardous vapors during a fire.



5. FIRE - FIGHTING MEASURES

Protective Equipment for Fire-Fighting

Wear full protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

No specific measures recommended.

Environmental Precautions

Prevent the material from entering drains or watercourses.

Methods and materials for containment and cleaning up

Pick up and dispose of in accordance with all applicable local and national regulations. Prevent the material from entering drains or watercourses.

7. HANDLING AND STORAGE

Precautions for safe handling

Wear appropriate protective clothing.

Conditions for safe storage

Store in original container at temperatures between 68°F and 77°F (20°C - 25°C). Store away from children and pets.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure limits are listed below, if they exist.

Appropriate engineering controls

No specific measures necessary. Good general room ventilation is expected to be adequate to control airborne levels.

Individual protection measures**Respiratory Protection**

Not required under normal conditions of use.

Skin Protection

Not required under normal conditions of use.

Eye/Face Protection

Not required under normal conditions of use.

Body Protection

Normal work wear.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State Solid

Color Brown

Odor Bacon

Odor Threshold No data available



9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|-------------------|
| pH | Not applicable |
| Density | No data available |
| Boiling Range/Point (°C/F) | Not applicable |
| Melting Point (°C/F) | Not applicable |
| Flash Point (PMCC) (°C/F) | Not applicable |
| Vapor Pressure | Not applicable |
| Evaporation Rate (BuAc=1) | Not applicable |
| Solubility in Water | No data available |
| Vapor Density (Air = 1) | Not applicable |
| VOC | Not applicable |
| Partition coefficient (n-octanol/water) | Not applicable |
| Viscosity | Not applicable |
| Auto-ignition Temperature | No data available |
| Decomposition Temperature | No data available |
| Upper explosive limit | No data available |
| Lower explosive limit | No data available |
| Flammability (solid, gas) | No data available |

10. STABILITY AND REACTIVITY

Reactivity

Data is not available

Chemical Stability

Stable under normal conditions.

Possibility of hazardous reactions

Hazardous reactions will not occur.

Conditions to Avoid

Heat - high temperatures

Incompatible Materials

None known.

Hazardous Decomposition Products

Oxides of carbon- nitrogen oxides - sulfur oxides

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Ivermectin:

Oral LD50 (rat) 50 mg/kg

Oral LD50 (human) >15mg/kg

Dermal LD50 406 mg/kg (rabbit)

Pyrantel Pamoate

Oral LD50 (rat) >2000 mg/kg

Praziquantel:

Oral LD50 (rat) 2840 mg/kg



11. TOXICOLOGICAL INFORMATION

Specific Target Organ Toxicity (STOT) – single exposure

Ivermectin: At high doses in humans and animals vomiting, tachycardia, blood pressure fluctuation, CNS effects (somnolence, ataxia) and visual disturbances have been observed. Higher doses may cause death due to respiratory depression.

Specific Target Organ Toxicity (STOT) – repeat exposure

No relevant studies identified.

Serious Eye damage/Irritation

Ivermectin: Slightly irritating to eyes in rabbit tests.

Praziquantel: Not irritating to eyes in rabbit studies.

Skin Corrosion/Irritation

Ivermectin: Non-irritating in animal studies.

Praziquantel: Not irritating to skin in rabbit studies.

Respiratory or Skin Sensitization

Ivermectin: Hypersensitivity reactions have been reported in humans.

Praziquantel: Not sensitizing to skin in guinea pig study.

Carcinogenicity

Not considered carcinogenic by NTP, IARC, and OSHA.

Germ Cell Mutagenicity

Pyrantel Pamoate: Ames test in *S. typhimurium* Result: Negative. Murine Sperm-head abnormality test Result: Positive.

Ivermectin: Negative in the AMES Assay, and in a mouse lymphoma mutation assay. In addition, it did not induce unscheduled DNA synthesis in a human fibroblast cell culture, suggesting that it does not damage DNA.

Praziquantel: Negative results for in vivo and in vitro animal studies.

Reproductive Toxicity

Pyrantel Pamoate: No evidence of adverse effects on fertility, reproduction or lactation was observed in rats at oral doses of 250 mg/kg/day. No maternal toxicity, embryo or fetotoxicity were observed in perinatal and postnatal toxicity study.

Ivermectin: Teratogenic in rats, rabbit and mice at or near materno-toxic dose levels. The abnormalities are limited mainly to cleft palate.

Praziquantel: Studies in rats and rabbits have shown no evidence of impaired fertility or harm to the fetus. An increase of the abortion rate was found in rats at three times the single human therapeutic dose.

Aspiration Hazard

Not an aspiration hazard.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ivermectin

LC50 (Trout) 0.003mg/l 96hr

LC50 (*Daphnia magna*) 0.000025mg/l 48hr

Praziquantel: Chronic Aquatic Toxicity: Category 3



12. ECOLOGICAL INFORMATION

Mobility in soil

Ivermectin: Ivermectin is metabolized in the soil. Water solubility is limited and it binds to soil very tightly. It does not bioconcentrate in fish and is not taken up from soil into plants.

Persistence/Degradability

Ivermectin: Slow biodegradation. Photodegrades rapidly.

Bioaccumulative Potential

No relevant studies identified.

Other adverse effects

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with all applicable local and national regulations.

14. TRANSPORT INFORMATION

Contact supplier for transport information.

15. REGULATORY INFORMATION

United States TSCA Inventory

This product is excluded from the US EPA Toxic Substance Control Act and is regulated under the Food, Drug and Cosmetic Act.

California Proposition 65

This product does not contain any Proposition 65 chemicals at levels which would require warning labels as known to the State of California to cause cancer, birth defects or other reproductive harm.

SARA Title III Sect. 311/312 Categorization

None

SARA Title III Sect. 313

This product contains a chemical that is listed in Section 313 at or above de minimis concentrations. The following listed chemicals are present: None

16. OTHER INFORMATION

Legend

ACGIH: American Conference of Governmental Industrial Hygienists

CAS#: Chemical Abstracts Service Number

FIFRA: Federal Insecticide, Fungicide and Rodenticide Act

IARC: International Agency for Research on Cancer

LC50: Lethal Concentration 50%

LD50: Lethal Dose 50%

N/A: Denotes no applicable information found or available

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration



16. OTHER INFORMATION

Legend, cont.

PEL: Permissible Exposure Limit

STEL: Short Term Exposure Limit

TLV: Threshold Limit Value

TSCA: Toxic Substance Control Act

Revision Date: September 30, 2017

Replaces: This is the first issue.

Changes made: Not applicable.

Information Source and References

This SDS is prepared by Hazard Communication Specialists based on information provided by internal company references.

Prepared By: EnviroNet LLC.

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