SAFETY DATA SHEETS

This SDS packet was issued with item:

078950498

N/A

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: AYRADIA™ (metronidazole oral suspension) for dogs 125 mg/mL

Manufacturer Name: Virbac AH, Inc.
Address: P.O. Box 162059
Fort Worth, TX 76161 USA

Telephone number: 1-800-338-3659

Emergency phone number: CHEMTREC: (800) 424-9300
Human Toll-free 833-224-2009
Animal Toll-free 833-224-2013

Recommended use: Animal drug
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Germ Cell Mutagen Category 2 Carcinogenicity Category 1B

Label Elements:
Warning!

Hazard statement(s)
Suspected of causing generic defects.
May cause cancer.

Precautionary statement(s)
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective clothing and gloves.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

Other Hazards: None known

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Metronidazole	443-48-1	10-15%
Medium Chain Triglycerides	73398-61-5	Proprietary
Poultry Liver Powder	Mixture	Proprietary
Stearic Acid	57-11-4	Proprietary
Aluminum Stearate	1471315-26-0	Proprietary
Butylated Hydroxytoluene	128-37-0	<0.1%

The exact percentage is a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact: Wash skin with soap and water. If irritation or symptoms develop, get medical attention.
Eye contact: If eye contact occurs, immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: If swallowed, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Ingestion may cause gastrointestinal distress. Inhalation of mists may cause upper respiratory tract irritation. The most serious adverse reactions reported in patients treated with metronidazole have been convulsive seizures, encephalopathy, aseptic meningitis, optic and peripheral neuropathy, the latter characterized mainly by numbness or paresthesia of an extremity. In addition, patients have reported headache, syncope, dizziness, vertigo, incoordination, ataxia, confusion, dysarthria, irritability, depression, weakness, and insomnia. Suspected of causing genetic effects. May cause cancer. The risk of cancer depends on the level and duration of exposure.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is generally not required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but may burn under fire conditions. Combustion products may be hazardous.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spills from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Absorb with an inert absorbent and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists in handling. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging
Keep away from children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Metronidazole	None Established
Medium Chain Triglycerides	None Established
Poultry Liver Powder	None Established
Stearic Acid	None Established
Aluminum Stearate	3 mg/m3 (respirable) 10 mg/m3 (inhalable) TWA ACGIH TLV
Butylated Hydroxytoluene	2 mg/m3 (inhalable fraction and vapor) TWA ACGIH TLV

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: Impervious gloves recommended if needed to avoid skin contact and for bulk processing.
Eye protection: None required for normal use. Chemical safety goggles recommended for bulk processing.
Other: Impervious clothing recommended if needed to avoid skin contact and for bulk processing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Yellowish liquid.
Odor: None

Odor threshold: Not applicable	**pH:** Not determined
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: >200°F	**Evaporation rate:** Not determined
Flammability (solid, gas): Not flammable	**VOC:** 0%
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Not determined	**Vapor density:** Not determined
Relative density: Not determined	**Solubility(ies):** Not available
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.
Ingestion: Swallowing may cause gastrointestinal distress with nausea and diarrhea.
Skin contact: No adverse effects are expected. Minor irritation is possible.

Eye contact: Contact may cause slight irritation with redness and tearing.
Chronic Effects: None known.
Sensitization: Components are not sensitizers.
Germ Cell Mutagenicity: Metronidazole induces gene mutations in various test systems and microbial fungi, as well as mitotic gene conversion in yeast. In hypoxic conditions were observed chromosomal mutations in mammalian cells. The substance induces chromosomal mutations in mice in vivo. In systems of indicators (UDS) occurred genotoxic effects in human and rat primary hepatocytes in vitro. Recent studies in humans indicate a genotoxic mechanism in vivo. At concentrations below the therapeutic plasma concentrations, in vitro, were seen genotoxic effects in human lymphocytes. Also, genotoxic effects (chromosome aberration in peripheral lymphocytes) in humans after oral treatment with metronidazole are known. None of the other components have been shown to cause germ cell mutagenicity.
Reproductive Toxicity: Fertility studies have been performed in mice up to six times the recommended human oral dose and have revealed no evidence of impaired fertility. No evidence of impaired fertility or adverse effects on the fetus were observed in rats exposed to metronidazole at doses that were up to 5 times the maximum human dose. Similarly, no fetal toxicity was observed following oral administration of metronidazole to pregnant mice at 20 mg/kg/day, but some intrauterine deaths were observed in a single small study where the drug was administered intraperitoneally. Metronidazole has been shown to cross the placental barrier.
Carcinogenicity: Metronidazole has shown evidence of carcinogenic activity in a number of studies involving chronic oral administration in mice and rats. Prominent among the effects in the mouse was the promotion of pulmonary tumorigenesis. This has been observed in all six reported studies in that species, including one study in which the animals were dosed on an intermittent schedule (administration during every fourth week only). At very high dose levels (approximately 500 mg/kg/day), there was a statistically significant increase in the incidence of malignant liver tumors in males. Also, the published results of one of the mouse studies indicate an increase in the incidence of malignant lymphomas as well as pulmonary neoplasms associated with lifetime feeding of the drug. All these effects are statistically significant. Several long-term oral dosing studies in the rat have been completed. There were statistically significant increases in the incidence of various neoplasms, particularly in mammary and hepatic tumors, among female rats administered metronidazole over those noted in the concurrent female control groups. Two lifetime tumorigenicity studies in hamsters have been performed and reported to be negative. Metronidazole is classified by IARC as a potential carcinogen (Group 2B) and by NTP as reasonably anticipated to be a carcinogen. None of the other components present at 0.1% or greater are listed as carcinogens by IARC, NTP or OSHA.
Acute Toxicity Values: Metronidazole: Oral rat LD50 >2000 mg/kg.

12. ECOLOGICAL INFORMATION

Ecotoxicity values: Metronidazole: LC50 Cyprinodon variegatus (Sheepshead minnow) 1060 mg/L/96 hr; EC50 Daphnia magna >1000 mg/L/48hr; EC50 Pseudokirchneriella subcapitata 40.4 mg/L/72 hr
Persistence and degradability: Metronidazole if not readily biodegradable.
Bioaccumulative potential: Metronidazole Log Pow 0.02 – not expected to bioaccumulate.
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			No
IMDG		Not Regulated			No

IATA		Not Regulated			No

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification.

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None
EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**

16. OTHER INFORMATION

SDS Revision History: New SDS.
Date of preparation: November 1, 2023

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