



ANIMAL HEALTH

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Safety Data Sheet

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2024 and GHS Rev 07

Date of issue: 06/09/2025

Revised on 06/09/2025

* 1 Identification

· **Product Identifier**

· **Trade Name:** AIVLOSIN® (62.5% w/w tylvalosin) Water Soluble Granules

· **Relevant identified uses of the substance or mixture and uses advised against:**

· **Product Description:**

Veterinary antibiotic powder for preparation of medicated drinking water for animals. Not for human use.

Chemical Family: Antibiotic, macrolide class

Synonyms:

Tylvalosin tartrate (approved non-proprietary name)

3-O-acetyl-4"-O-isovaleryltylosin tartrate

Acetylisovaleryltylosin tartrate

AIVT tartrate

AIV tartrate

· **Details of the Supplier of the Safety Data Sheet:**

· **Manufacturer/Supplier:**

ECO Animal Health

Building 12

11224 Aurora Avenue

Urbandale, IOWA, 50322, USA

Tel: 1-609-683-9030 Fax: 1-609-683-3727

The Grange, 100 The High Street

Southgate, London N14 6BN, UK

Tel: +44 (0) 20 8447 8899 Fax: +44 (0) 20 8447 9292

www.ecoanimalhealth.com

email: sales@ecoanimalhealth.com

· **Emergency telephone number:**

Pharmgate Animal Health LLC

Telephone: 1-833-531-0114 , 1-800-380-6099

Hours: 24 Hours a Day/7 Days a week

* 2 Hazard(s) Identification

· **Classification of the substance or mixture:**



Specific target organ toxicity (single exposure) 3 H335 May cause respiratory irritation.

· **Label elements:**

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard statements:**

H335 May cause respiratory irritation.

· **Precautionary statements:**

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

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- P271 Use only outdoors or in a well-ventilated area.
P304+P340 If inhaled: Remove person to fresh air and keep comfortable for breathing.
P312 Call a poison center/doctor if you feel unwell.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Unknown acute toxicity:

This value refers to knowledge of known, established toxicological or ecotoxicological values.

0 % of the mixture consists of component(s) of unknown toxicity.

· Information pertaining to particular dangers for man and environment:**· Classification system:** NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme**· NFPA ratings (scale 0 - 4)**

Health = 1

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Physical Hazard = 0

· Hazard(s) not otherwise classified (HNOC): None known**· Classification according to (d)(1)(ii) of § 1910.1200**

The SDS issuer does not object to the classifications provided by importers or manufacturers of precursor products.

· Hazards not otherwise classified

There are no adverse physical or health effects known that are not covered by the hazard classes of the Hazard Communications Standard.

*** 3 Composition/Information on Ingredients****· Non-hazardous components:**

63409-12-1	Tylvalosin (free base)	96%
63428-13-7	Tylvalosin (tartrate)	

· Chemical characterization: Substance**· Description:**

Mixture of substances listed with non-hazardous additions and/or components that are less than listing threshold. All non-hazardous, components listed under threshold, and listed component total 100%.

· Dangerous Components: Non-Regulated Material**· Additional information:**

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

4 First-Aid Measures**· Description of first aid measures****· General information:** If symptoms persist, call a physician.**· After inhalation:**

Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in the side position for transportation.

· After skin contact: If skin irritation occurs, consult a doctor.

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Rinse opened eye for several minutes under running water.

If eye irritation occurs, consult a doctor.

· After swallowing: If swallowed and symptoms occur, consult a doctor.**· Most important symptoms and effects, both acute and delayed:** No further relevant information available.**· Indication of any immediate medical attention and special treatment needed:**

No further relevant information available.

5 Fire-Fighting Measures**· Extinguishing media****· Suitable extinguishing agents:** Use fire fighting measures that suit the environment.**· For safety reasons unsuitable extinguishing agents:** No further relevant information.**· Special hazards arising from the substance or mixture:**Maximum rate of Pressure Rise (P_{max}): 7.3 bargSpecific Material Constant (K_{st}): 146 bar.m/sec

Dust Explosion Class: St. 1

Minimum Ignition Energy (MIE): 300-1000 mJ.

· Advice for firefighters**· Special protective equipment for firefighters:**

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6 Accidental Release Measures**· Personal precautions, protective equipment and emergency procedures:**

Ensure adequate ventilation.

Avoid breathing dust.

· Environmental precautions: No special measures required.**· Methods and material for containment and cleaning up:**

Dispose of contaminated material as waste according to section 13.

Ensure adequate ventilation.

Dispose of the collected material according to regulations.

· PAC-1:

None of the ingredients are listed.

· PAC-2:

None of the ingredients are listed.

· PAC-3:

None of the ingredients are listed.

· Reference to other sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and Storage**· Precautions for safe handling:**

Avoid creating and breathing dust/fume/gas/mist/vapors/spray.

Ensure good ventilation/exhaustion at the workplace.

· Information about protection against explosions and fires: No special measures required.

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- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool, dry place.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s):** No further relevant information available.

* 8 Exposure Controls/Personal Protection

- **Control parameters:**
- **Components with occupational exposure limits:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
- **Exposure controls:**
Provide general ventilation in processing and storage. Provide local exhaust if necessary to reduce dust levels below acceptable limits.
- **Appropriate engineering controls** No further data; see section 7.
- **Personal protective equipment**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing and wash before reuse.
Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

- **Material of gloves:**
Latex or vinyl
PVC gloves
- **Penetration time of glove material:** Not applicable.
- **Eye protection:**



Safety glasses

- **Limitation and supervision of exposure into the environment:** None

* 9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Color:** White to off white
- **Odor:** No data available
- **Odor threshold:** Not determined.
- **Melting point/Melting range:** 125-129 °C (257-264.2 °F)
- **Boiling point/Boiling range:** Not determined.

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· Flammability:	Not determined.
· Explosion limits:	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	None
· Auto igniting:	Not applicable
· Decomposition temperature:	Not determined.
· pH-value @ 20 °C (68 °F):	3.5-5
· Viscosity:	
· Kinematic:	Not applicable.
· Dynamic:	Not applicable.
· Solubility in / Miscibility with:	
· Water:	Organic Solvent Solubility: Methanol 387 g/L at 25° C Ethanol 220 g/L at 25° C Acetonitrile 331 g/L at 25° C Ethyl acetate 77 g/L at 25° C Acetone 301 g/L at 25° C Ether 2.4 g/L at 25° C Chloroform 274 g/L at 25° C n-Hexane 0.013 g/L at 25° C
· Partition coefficient (n-octanol/water):	3.82 log POW
· Vapor pressure:	Not applicable.
· Vapor pressure:	
· Density:	Not determined.
· Relative density:	Not determined.
· Vapor density:	Not applicable.
· Particle characteristics	Not determined.
· Other information:	
· Appearance:	
· Form:	Powder
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not self-igniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Solvent content:	
· VOC content:	0.00 %
· Change in condition	
· Evaporation rate:	Not applicable.

10 Stability and Reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Product is stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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* 11 Toxicological Information

· **Information on toxicological effects:**

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

63409-12-1 Tylvalosin (free base)

Oral	LD50	>750 mg/kg (mouse) Bodyweight (respiratory disturbance, salivation, locomotor effects, reduced growth rate) >3,016 mg/kg (Rat) Bodyweight (respiratory disturbance, salivation, locomotor effects, reduced growth rate)
Inhalative	LC50/96 hours	>100 mg/l (Trout)

· **Primary irritant effect:**

· **On the skin:**

In an occluded 4 hr exposure test in rabbits, a 1% saline solution of Aivlosin tartrate was non-irritating. A 10% saline solution was mildly irritating to the skin.

· **On the eye:** No irritating effect.

· **Sensitization:**

In a Guinea pig maximization assay (Magnusson-Kilgmann) 12 of 20 animals showed discreet or patchy erythema following challenge. Aivlosin tartrate is considered to be a mild sensitizer.

· **Germ cell mutagenicity**

No evidence of mutagenic potential in bacterial and mammalian cell gene mutation assays. In in vitro cell culture assays structural chromosomal damage was observed in two studies, however, in three in vivo tests, no evidence of chromosomal damage was observed.

· **Carcinogenicity** Studies were not required as short term tests showed no relevant adverse effects.

· **Reproductive toxicity**

There were no adverse effects on parameters of reproduction in rats fed tylvalosin in the diet up to 10,000 ppm, a dose which produced maternal toxicity. Fetuses from the 10,000 ppm dose group had slightly reduced body weights. NOEL 400 ppm (approx 18 mg tylvalosin/kg bodyweight).

Developmental toxicity studies in rats and mice showed slightly reduced fetal body weights, but only at doses which were maternally toxic. There was no evidence of other developmental effects and no evidence of teratogenic effects in either species.

· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· **Interactive effects** No interactive effects between components are known.

· **Carcinogenic categories:**

· **IARC (International Agency for Research on Cancer):**

None of the ingredients are listed.

· **NTP (National Toxicology Program):**

None of the ingredients are listed.

· **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

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· **Alternative sources for toxicological information**

No non-standard sources for toxicological information where used.

12 Ecological Information

· **Toxicity:**

· **Aquatic toxicity:**

63409-12-1 Tylvalosin (free base)

EC50 617 mg/l (Daphnia)

· **Persistence and degradability:** No further relevant information available.

· **Bioaccumulative potential:** No further relevant information available.

· **Mobility in soil:** No further relevant information available.

· **Results of PBT and vPvB assessment:**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects:**

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

13 Disposal Considerations

· **Waste treatment methods**

· **Recommendation:**

Observe all federal, state and local environmental regulations when disposing of this material.

· **Uncleaned packaging**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport Information

· **UN-Number:**

· **DOT, ADR/ADN, IMDG, IATA**

Non-Regulated Material

· **UN proper shipping name:**

· **DOT, ADR/ADN, IMDG, IATA**

Non-Regulated Material

· **Transport hazard class(es):**

· **DOT, ADR/ADN, ADN, IMDG, IATA**

· **Class:**

Non-Regulated Material

· **Packing group:**

· **DOT, ADR/ADN, IMDG, IATA**

Non-Regulated Material

· **Environmental hazards:**

Not applicable.

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:**

Not applicable.

· **Special precautions for user:**

Not applicable.

· **UN "Model Regulation":**

Non-Regulated Material

15 Regulatory Information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture:**

No further relevant information available.

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· **SARA (Superfund Amendments and Reauthorization):**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

None of the ingredients are listed.

· **Hazardous Air Pollutants**

None of the ingredients are listed.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

· **New Jersey Right-to-Know List:**

None of the ingredients are listed.

· **New Jersey Special Hazardous Substance List:**

None of the ingredients are listed.

· **Pennsylvania Right-to-Know List:**

None of the ingredients are listed.

· **Pennsylvania Special Hazardous Substance List:**

None of the ingredients are listed.

· **Carcinogenic categories:**

· **EPA (Environmental Protection Agency):**

None of the ingredients are listed.

· **TLV (Threshold Limit Value established by ACGIH):**

None of the ingredients are listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health):**

None of the ingredients are listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:**



· **Signal word:** Warning



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· **Hazard statements:**

H335 May cause respiratory irritation.

· **Precautionary statements:**

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

P271 Use only outdoors or in a well-ventilated area.

P304+P340 If inhaled: Remove person to fresh air and keep comfortable for breathing.

P312 Call a poison center/doctor if you feel unwell.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **National regulations:**

The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Date of previous version** 09/26/2023

· **Version number of previous version:** 1

· **Date of preparation** 06/09/2025

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety and Health

OSHA: Occupational Safety & Health Administration

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Specific target organ toxicity (single exposure) 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**

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