

## Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 05/18/2021

Reviewed on 05/18/2021

### \* 1 Identification

· **Product Identifier**

· **Trade Name: AIVLOSIN® (17% Tylvalosin) Type A Medicated Article (Premix)**

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

· **Product Description:**

Type A Medicated Article (Premix) containing a veterinary antibiotic and used for preparation of medicated feeds 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

344 Nassau Street

Princeton, NJ 08540, USA

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

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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:**



STOT SE 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.

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

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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.

· **Classification system:** NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

· **NFPA ratings (scale 0 - 4)**



· **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

### 3 Composition/Information on Ingredients

· **Non-hazardous components:**

|            |                        |     |
|------------|------------------------|-----|
| 63409-12-1 | Tylvalosin (free base) | 20% |
| 63428-13-7 | Tylvalosin (tartrate)  |     |

· **Chemical characterization: Substance**

· **Description:** Mixture of substances listed below with non-hazardous additions.

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

### 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.

· **After eye contact:**

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.

· **Information for 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.

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· **Special hazards arising from the substance or mixture:**

- Maximum rate of Pressure Rise (Pmax): 7.3 barg
- Specific Material Constant (Kst): 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.

· **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.

· **Protective Action Criteria for Chemicals**

· **PAC-1:**

None of the ingredients are listed.

· **PAC-2:**

None of the ingredients are listed.

· **PAC-3:**

None of the ingredients are listed.

### 7 Handling and Storage

· **Handling**

· **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.

· **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

· **Additional information about design of technical systems:** No further data; see section 7.

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· **Control parameters:**

· **Components with occupational exposure limits:**

**AVILOSIN® Type A Medicated Article (Premix) (1%)**

|     |  |
|-----|--|
| TWA | Short-term value: 5 mg/m <sup>3</sup> (8 hr.)<br>Heubach Type I Dust meter |
|-----|--|

· **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.

· **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:** Not required.

· **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**

· **Appearance:**

**Form:** Powder

**Color:** Off-white to light brown

· **Odor:** Not determined.

· **Odor threshold:** Not determined.

· **pH-value @ 20 °C (68 °F):** 3.5-5

· **Change in condition**

**Melting point/Melting range:** 125-129 °C (257-264.2 °F)

· **Flash point:** None

· **Flammability (solid, gaseous):** Not determined.

· **Ignition temperature:** Not applicable

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

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- **Explosion limits:**
  - Lower:** Not determined.
  - Upper:** Not determined.
- **Vapor pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density:** Not determined.
- **Vapor density:** Not applicable.
- **Evaporation rate:** 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
- **Viscosity:**
  - Dynamic:** Not applicable.
  - Kinematic:** Not applicable.
- **Solvent content:**
  - VOC content:** 0.00 %
- **Other information:** No further relevant information available.

**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.

**\* 11 Toxicological Information**

- **Information on toxicological effects:**
- **Acute toxicity:**

| · <b>LD/LC50 values that are relevant for classification:</b> |               |  |
|---|---------------|--|
| <b>63409-12-1 Tylvalosin (free base)</b>                      |               |  |
| Oral  | LD50          | >750 mg/kg (Mouse)<br>Bodyweight (respiratory disturbance, salivation, locomotor effects, reduced growth rate)<br>>3,016 mg/kg (Rat)<br>Bodyweight (respiratory disturbance, salivation, locomotor effects, reduced growth rate) |
| Inhalative  | LC50/96 hours | >100 mg/l (Trout)  |

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· **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.

· **Additional toxicological information:**

· **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.

· **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.

### 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.

· **Behavior in environmental systems:**

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

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

· **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.

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

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects:** No further relevant information available.

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### 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.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** 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.
- **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.

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|  |
|--|
| · <b>New Jersey Right-to-Know List:</b>                                    |
| None of the ingredients are listed.  |
| · <b>New Jersey Special Hazardous Substance List:</b>                      |
| None of the ingredients are listed.  |
| · <b>Pennsylvania Right-to-Know List:</b>                                  |
| None of the ingredients are listed.  |
| · <b>Pennsylvania Special Hazardous Substance List:</b>                    |
| None of the ingredients are listed.  |
| · <b>Carcinogenic categories:</b>  |
| · <b>EPA (Environmental Protection Agency):</b>                            |
| None of the ingredients are listed.  |
| · <b>TLV (Threshold Limit Value established by ACGIH):</b>                 |
| None of the ingredients are listed.  |
| · <b>NIOSH-Ca (National Institute for Occupational Safety and Health):</b> |
| 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
- **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.

|                                     |
|-------------------------------------|
| · <b>National regulations:</b>      |
| None of the ingredients are listed. |

- **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.

- **Contact:**
- **Date of last revision/ revision number:** 05/18/2021 / 5
- **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



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DOT: US Department of Transportation  
IATA: International Air Transport Association  
EINECS: European Inventory of Existing Commercial 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  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

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