# MATERIAL SAFETY DATA SHEET

## Section 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

**SUBSTANCE:**

| | |
|---|---|
| **Trade Name** | **AIVLOSIN® (17% Tylvalosin) Type A Medicated Article (Premix)** |
| **Chemical Family:** | Antibiotic, macrolide class |
| **Synonyms:** | Tylvalosin tartrate (approved non-proprietary name)<br>3-O-acetyl-4"-O-isovaleryltylosin tartrate<br>Acetylisovaleryltylosin tartrate<br>AIVT tartrate<br>AIV tartrate |
| **Therapeutic Use:** | Type A Medicated Article (Premix) containing a veterinary antibiotic and used for preparation of medicated feeds for animals. Not for human use. |

**CONTACT INFORMATION:**

**FOR EMERGENCIES IN USA OR CANADA CONTACT:**

**ASPCA Animal Product Safety Service**

**Telephone: 1-800-345-4735**

**Hours: 24 Hours a Day/ 7 Days a week**

## Section 2. COMPOSITION/INFORMATION ON INGREDIENTS

| **COMPONENT 1** | |
|---|---|
| **Common Name:** | Tylvalosin tartrate (approved non-proprietary name) |
| **Chemical Name:** | (-)-(4*R*,5*S*,6*S*,7*R*,11*E*,13*E*,15*S*,16*R*)-15-[[(6-deoxy-2,3-di-*O*-methyl-β-D-*allo*pyranosyl)oxy]methyl]-6-[[3,6,-dideoxy-4-*O*-[2,6-dideoxy-3-*C*-methyl-4-*O*-(3-methylbutanoyl)-α-L-*ribo*-hexopyranosyl]-3-(dimethylamino)-β-D-*gluco*pyranosyl]oxy]-4-acetoxy-16-ethyl-5,9,13-trimethyl-2,10-dioxooxacyclohexadeca-11,13-diene-7-acetaldehyde(2*R*,3*R*)-tartrate |
| **CAS Registry No.:** | 63409-12-1 (free base)<br>63428-13-7 (tartrate) |
| **Percent by Weight:** | 20 % w/w |

| **COMPONENT 2** | **Non-Hazardous Inert Ingredients** |
|---|---|
| **Percent by Weight:** | ~ 80 % w/w |

## Section 3. HAZARDS IDENTIFICATION

**PRIMARY ROUTES OF EXPOSURE:**

| | |
|---|---|
| **SKIN CONTACT:** | Probable, if protective clothing, gloves are not worn during handling. |
| **EYE CONTACT:** | Possible, if goggles are not worn during handling |
| **INHALATION:** | Probable, if dust mask is not worn during handling. |
| **INGESTION:** | Low likelihood. Avoid eating, chewing of gum and smoking during handling. |
| **EFFECTS OF OVEREXPOSURE** | Overexposure to dust may cause respiratory effects including coughing, sneezing or wheezing. |

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## Section 4. FIRST AID MEASURES

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|---|---|
| **SKIN CONTACT:** | Wash hands and exposed skin after working and before eating |
| **EYE CONTACT:** | Wash eyes immediately with water. Seek medical attention if irritation persists. |
| **INHALATION:** | Remove individual from area of exposure; supportive treatment. |
| **INGESTION:** | Treat symptomatically; induction of vomiting may not be needed. |
| **NOTE TO PHYSICIAN:** | AIVLOSIN® (17% Tylvalosin) Type A Medicated Article (Premix) has a low toxicity. In cases of idiosyncratic reactions following exposure or accidental ingestion, treat symptomatically. |
| **ANTIDOTES:** | No data available. |

## Section 5. FIRE FIGHTING MEASURES

**FIRE CONTROL:**

| | |
|---|---|
| **Extinguisher Media:** | Water |
| **Fire Fighting Instructions:** | Use spray |
| **Extinguisher Media To Avoid:** | None known |

**FIRE AND EXPLOSION HAZARDS:**

| | |
|---|---|
| **Flash Point:** | Data not available |
| **Minimum Concentration Explosion Limit:** | Data not available |
| **Upper Explosion Limit:** | Data not available |
| **Hazardous Combustion Products:** | The creation of a dust cloud of organic material of any origin may form an explosive mixture with air. |

## Section 6. ACCIDENTAL RELEASE MEASURES

| | |
|---|---|
| **General Measures:** | Review Sections 3, 8 and 12 before proceeding with clean-up. |
| **Small Spill:** | Wear dust mask, overalls, gloves and sweep up spilled material. |
| **Large Spill:** | Wear dust mask, overalls, gloves and sweep up spilled material. |

## Section 7. HANDLING AND STORAGE

| | |
|---|---|
| **General Handling** | Minimize creation of dust; Close bag tightly after use. |
| **Storage Conditions** | Cool, dry conditions |
| **Temperature Range for Storage** | At or below 25°C (77°F) |

## Section 8. EXPOSURE LIMITS / PERSONAL PROTECTION

**Exposure Limits:**

| Compound | Issuer: | Type: | OEL: |
|---|---|---|---|
| AVILOSIN® Type A Medicated Article (Premix) | ECO Animal Health | TWA-8 hr. | 5 mg/8 hr as respirable dust |
| **Measurement Method** | | Heubach Type 1 Dust meter | |

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## Section 8. EXPOSURE LIMITS / PERSONAL PROTECTION (Continued)

| | |
|---|---|
| **Personal Protection:** | |
| **Ventilation** | Ventilation recommended to reduce respirable dust below TWA |
| **Respiratory Protection:** | Dust Mask |
| **Eye Protection:** | Goggles |
| **Skin Protection:** | Overalls |
| **Hand protection:** | Gloves (*e.g.*, latex, polyethylene) |
| **Other Protective Equipment:** | None |

The information in the following sections apply to Tylvalosin Tartrate except as indicated.

## Section 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | | |
|---|---|---|---|---|
| **Physical Form / Appearance** | Off-white to light brown powder (Premix) | | | |
| **Odor Threshold** | No information available | | | |
| **Molecular Weight** | 1042.27 (free base)<br>1192.27 (tartrate) | | | |
| **Molecular Formula** | $C_{53}H_{87}NO_{19}C_4H_6O_6$ | | | |
| **pH** | 3.5 – 5.0 | | | |
| **Melting Point** | 125-129°C | | | |
| **Boiling Point** | Not applicable | | | |
| **Water Solubility** | 948 g/L at 25 ± 2°C | | | |
| **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 |
| **Vapor Pressure** | No information available. As a high molecular weight solid material, this material is not expected to possess a significant vapor pressure. | | | |
| **Octanol:Water Partition Coefficient (log $P_{ow}$)** | 3.82 | | | |

## Section 10. STABILITY AND REACTIVITY

| | |
|---|---|
| **Reactivity:** | None known |
| **Conditions To Avoid:** | See Explosive Properties |
| **Incompatibility:** | None known |
| **Flammability:** | Not applicable (see Explosive Properties) |
| **Explosive Properties:** | The creation of a dust cloud of organic material of any origin may form an explosive mixture with air. |
| **Hazardous Polymerization:** | None known – unlikely |
| **Hazardous Decomposition Products:** | None known – unlikely |

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## Section 11. TOXICOLOGY INFORMATION

| | |
|---|---|
| ORAL TOXICITY: | Mouse oral $LD_{50}$ >750 mg/kg bodyweight (respiratory disturbance, salivation, locomotor effects, reduced growth rate)<br>Rat oral $LD_{50}$ >3016 mg/kg bodyweight (respiratory disturbance, salivation, locomotor effects, reduced growth rate) |
| INHALATION TOXICITY: | No information available. Particle size analyses using Aivlosin® premix suggest that less than 5.7 % of dust particles are inhalable and less than about 2.3% could penetrate the lungs. |
| SKIN IRRITATION: | 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. |
| 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. |
| GENOTOXICITY: | 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 EFFECTS: | 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. |
| IMMUNOTOXICOLOGIC EFFECTS: | No evidence in several repeated dose studies that tylvalosin has any adverse effect on the components of the immune system (e.g. thymus, spleen, lymph nodes). There was no evidence of increased incidences of infections. |
| PHARMACOLOGIC EFFECTS: | Macrolides interfere with protein synthesis by binding reversibly to the 50S ribosome subunit. They bind to the donor site and prevent the translocation necessary to maintain the growth of peptide chains. |
| TARGET ORGAN EFFECTS: | None reported for this antimicrobial drug. |

## Section 12. ECOLOGICAL INFORMATION

**ENVIRONMENTAL FATE:**

**Mobility:** Poor, tylvalosin has a very strong affinity for soil
**Persistence / Degradability:** $DT_{50}$ (soil half life) <20 days
**Bioaccumulative Potential:** Low

**ECOTOXICITY:**

**Toxicity to Fish:** $LC_{50}$ >100 mg tylvalosin/L (rainbow trout)
**Toxicity to Daphnids:** 48 hr $EC_{50}$ = 617 mg tylvalosin/L;
**Toxicity to Plants:** $LC_{50}$ >1090 mg tylvalosin/kg soil

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## Section 13. DISPOSAL CONSIDERATIONS

Observe all federal, state and local regulations when disposing of this material. May be disposed of by landfill.

## Section 14. TRANSPORT INFORMATION

**DOT Considerations:** None established
**IMO Considerations:** None established
**IATA Considerations:** None established
**State Regulations:** None established
**Local Considerations:** None established

## Section 15. REGULATORY INFORMATION

This material is for the treatment of animals only
Keep out of the reach of children.
**OECD Harmonized Classification:** Xi; R43

## Section 16. OTHER INFORMATION

**HAZARD LABEL:** May cause skin irritation. Tylvalosin tartrate has been shown to cause hypersensitization in laboratory animals. Persons with known hypersensitivity should avoid contact with the product. In case of accidental ingestion, seek medical advice.

**OTHER INFORMATION:**
**EINECS NUMBER Component 1:** 264-132-2 (free base). Tartrate salt not listed
**EINECS NUMBER Component 2:** Not listed
**EINECS NUMBER Component 3:** Not listed

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ECO ANIMAL HEALTH

344 Nassau Street
Princeton, NJ 08540, USA
Tel: 1-609-683-9030 Fax: 1-609-683-3727
email: wrdodemaide@ecoanimalhealth.com

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