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) 3-O-acetyl-4"-O-isovaleryltylosin tartrate Acetylisovaleryltylosin tartrate AIVT tartrate 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) 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

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:

Maximum rate of Pressure Rise (P_{max})	7.3 barg
Specific Material Constant (K_{st})	146 bar.m/sec
Dust Explosion Class	St. 1
Minimum Ignition Energy (MIE)	300-1000 mJ.

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 I 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) 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. See Section 5 for more details.
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) 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

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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