# Tyloxan



## PRODUCT USE

A veterinary antibacterial used to treat sensitive mycoplasma organisms which are involved in causing chronic respiratory disease in chickens and sinus infections in turkeys. For prophylaxis used at the rate of one 550g sachet (500g tylosin tartrate activity) to 1000 I of drinking water for 21-35 day old broilers for 2-3 days; or, for treatment of high levels of Mycoplasma infection in day old birds, one sachet in 1500L for the first three days, repeating at 21-35 days. Also for the treatment of Breeders, pullets and turkeys. Mix and supply at manufacturer's direction.

## **SYNONYMS**

C46-H77-N-O17.C4-H6-O6, C46-H77-N-O17.C4-H6-O6, "tylosin, [(R-(\*, R\*)-2, 3-dihydroxybutanedioate]", "tylosin, [(R-(\*, R\*)-2, 3 -dihydroxybutanedioate]", "macrolide antibiotic/ antibacterial", "animal food additive", "veterinary therapeutic compound", "Elanco Products Tylosin Tartrate", "AFS Tylan Soluble", Pharmasin

## **Section 2 - HAZARDS IDENTIFICATION**

#### **CANADIAN WHMIS SYMBOLS**



EMERGENCY OVERVIEW RISK May cause SENSITIZATION by skin contact. Very toxic to aquatic organisms.

POTENTIAL HEALTH EFFECTS

**ACUTE HEALTH EFFECTS** 

#### SWALLOWED

Accidental ingestion of the material may be damaging to the health of the individual.

• Macrolides comprise a large group of antibiotics derived from Streptomyces spp. having in common a macrocyclic lactone ring to which one or more sugars are attached. They are all weak bases. The most common side effect produced by the family of macrolide antibiotics is gastrointestinal discomfort. Supra-infections may occur although these are rare. Several macrolides produced allergic sensitization but, again, these are rare. Symptoms include watery eyes, shortness of breath, nasal congestion, choking, coughing and wheezing. Allergic skin reactions have also occurred. Exposure to at least one member of the family, choking, coughing and wheezing. Allergic skin reactions have also occurred. Exposure to at least one member of the family, erythromycin, at high concentrations, has produced reversible deafness (ototoxicity). Systemic reactions including fever, rash, and lymph-node pain or swelling have been produced by the avermectin group. Ivermectin has produced ataxia (incoordination), lethargy, bradypnea (slowed breathing), vomiting, mydriasis (dilated pupils), sedation, tremors and death in animals. The avermectin group (anthelmintics, insecticides and acaricides) mediate the transmission of gamma-butyric acid (GABA), an inhibitory neurotransmitter, in mammals thus causing paralysis. Hepatotoxic effects with transient disturbances and jaundice have resulted from the use of oleandomycin. Transient alterations in heart rate/ rhythm have also been produced by several members of the family (notably tilmicosin). Heart muscle degeneration, characterized by small areas of cell death have also been reported in animals exposed to tilmicosin. Cross -resistance is often observed between the macrolide, lincosamide and streptogramin group of antibiotics.

■ Salts of tartaric acid (including Rochelle salt and Seidlitz powder) and the acid itself have all produced serious poisonings or fatalities in man. Gastrointestinal symptoms are marked and include violent vomiting, diarrhea, abdominal pain and thirst followed by cardiovascular collapse and/or kidney failure.

#### EYE

• Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

#### SKIN

• The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

Open cuts, abraded or irritated skin should not be exposed to this material.

• Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

#### INHALED

The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

#### **CHRONIC HEALTH EFFECTS**

• Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

There is some evidence that inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray. Exposure to small quantities may induce hypersensitivity reactions characterized by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic edema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non - thrombocytopenic purpura) may occur. An individual may be predisposed to such anti-body mediated reaction if other chemical agents have caused prior sensitization (cross-sensitivity).

Respiratory sensitization may result in allergic/asthma like responses; from coughing and minor breathing difficulties to bronchitis with wheezing, gasping.

Tylosin is mutagenic in one mammalian test system. Test in bacterial cell and other mammalian cells did not produce mutagenicity.

# Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

#### HAZARD RATINGS



# Section 4 - FIRST AID MEASURES

## **SWALLOWED**

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

EYE

- If this product comes in contact with the eyes:
- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

#### SKIN

- If skin contact occurs:
- Immediately remove all contaminated clothing, including footwear
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

## INHALED

- •
- If dust is inhaled, remove from contaminated area.
- Encourage patient to blow nose to ensure clear passage of breathing.
- If irritation or discomfort persists seek medical attention.

#### NOTES TO PHYSICIAN

Treat symptomatically.

## Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

#### **EXTINGUISHING MEDIA**

- Water spray or fog.
- Water spray or
   Foam.
- Toant.
   Druchomiz
- Dry chemical powder.BCF (where regulations permit).
- Carbon dioxide.
- FIRE FIGHTING

#### -

- Alert Emergency Responders and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

## **GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS**

- Combustible solid which burns but propagates flame with difficulty.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture
  with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding
  of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

# FIRE INCOMPATIBILITY

Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

# PERSONAL PROTECTION

Glasses: Safety Glasses. Chemical goggles. Gloves: Respirator: Particulate

# Section 6 - ACCIDENTAL RELEASE MEASURES

## MINOR SPILLS

- Environmental hazard contain spillage.
- Clean up waste regularly and abnormal spills immediately.
- · Avoid breathing dust and contact with skin and eyes.
- · Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosionproof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

MAJOR SPILLS

Environmental hazard - contain spillage.

- Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- · Recover product wherever possible.
- IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise emergency services.

#### PROTECTIVE ACTIONS FOR SPILL

## PROTECTIVE ACTION ZONE



## FOOTNOTES

1 PROTECTIVE ACTION ZONE is defined as the area in which people are at risk of harmful exposure. This zone assumes that random changes in wind direction confines the vapour plume to an area within 30 degrees on either side of the predominant wind direction, resulting in a crosswind protective action distance equal to the downwind protective action distance.

2 PROTECTIVE ACTIONS should be initiated to the extent possible, beginning with those closest to the spill and working away from the site in the downwind direction. Within the protective action zone a level of vapour concentration may exist resulting in nearly all unprotected persons becoming incapacitated and unable to take protective action and/or incurring serious or irreversible health effects.

Unable to take protective action and/or incurring serious or irreversible health effects.
3 INITIAL ISOLATION ZONE is determined as an area, including upwind of the incident, within which a high probability of localised wind reversal may expose nearly all persons without appropriate protection to life -threatening concentrations of the material.
4 SMALL SPILLS involve a leaking package of 200 litres (55 US gallons) or less, such as a drum (jerrican or box with inner containers). Larger packages leaking less than 200 litres and compressed gas leaking from a small cylinder are also considered "small spills". LARGE SPILLS involve many small leaking packages or a leaking package of greater than 200 litres, such as a cargo tank, portable tank or a "one -tonne" compressed gas cylinder.
5 Guide 171 is taken from the US DOT emergency response guide book.
6 IERG information is derived from CANUTEC - Transport Canada.

#### ACUTE EXPOSURE GUIDELINE LEVELS (AEGL) (in ppm)

AEGL 1: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.

AEGL 2: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

AEGL 3: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

# Section 7 - HANDLING AND STORAGE

## **PROCEDURE FOR HANDLING**

Avoid all personal contact, including inhalation.

- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately.
- Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

## **RECOMMENDED STORAGE METHODS**

- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

#### STORAGE REQUIREMENTS

Observe manufacturer's storing and handling recommendations.

## SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



X: Must not be stored together

O: May be stored together with specific preventions

+: May be stored together

# Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS	
US OSHA Permissible Exposure	Material
U us osha Permissible Exposure S Levels (PELs) - Table Z3	tylosin tartrate (Inert or Nuisance Dust: (d) Total dust)
	tylosin tartrate (Inert or Nuisance
r US-Hawaii Air Contaminant g	Dust: (d) Respirable fraction)
P e	tylosin tartrate (Inert or Nuisance Dust: (d) Total dust)
r m i	tylosin tartrate (Particulates not other wise
s s :	regulated - Total dust)
b I	tylosin tartrate (Particulates not other wise
E x	regulated - Respirable
р о	fraction)
s u	
r e	

T W	EL STEL Peak Peak	TWA Notes a	opm mg/m³ ppm mg/m	³ ppm	15		
A T W	10		*		10		
A S T	5				5		
	US - Oregon Permiss Exposure Limits (Z3)	sible	tylosin tartrate (Inert o Dust: (d) Respirable f	or Nuisance raction)	5	*	
	US - Tennessee Occ Exposure Limits - Lin Contaminants	upational nits For Air	tylosin tartrate (Partic otherwise regulated F fraction)	ulates not Respirable	5		
	US - Wyoming Toxic Hazardous Substanc Limits for Air Contam	and es Table Z1 iinants	tylosin tartrate (Partic otherwise regulated ( Respirable fraction)	ulates not PNOR)(f)-	5		
	US - Michigan Expos Air Contaminants	sure Limits for	tylosin tartrate (Partic otherwise regulated, Resp dust)	ulates not irable	5		

# MATERIAL DATA

TYLOSIN TARTRATE: Airborne particulate or vapor must be kept to levels as low as is practicably achievable given access to modern engineering

controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

## PERSONAL PROTECTION



Consult your EHS staff for recommendations

#### EYE

■ When handling very small quantities of the material eye protection may not be required.

- For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first -aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59]

#### HANDS/FEET

• NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- · chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- Rubber gloves (nitrile or low -protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- · Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocaoutchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

- OTHER
- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air -supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- · Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit
- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as
  part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

## RESPIRATOR

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Protection Factor	Half-Face Respirator	Full -Face Respirator	Powered Air Respirator
10 x PEL	P1	-	PAPR-P1
	Air-line*	-	-
50 x PEL	Air-line**	P2	PAPR-P2
100 x PEL	-	P3	-
		Air-line*	-
100+ x PEL	-	Air-line**	PAPR-P3

\* - Negative pressure demand \*\* - Continuous flow

Explanation of Respirator Codes: Class 1 low to medium absorption capacity filters.

Class 2 medium absorption capacity filters.

Class 3 high absorption capacity filters.

PAPR Powered Air Purifying Respirator (positive pressure) cartridge.

Type A for use against certain organic gases and vapors.

Type AX for use against low boiling point organic compounds (less than 65°C).

Type B for use against certain inorganic gases and other acid gases and vapors.

Type E for use against sulfur dioxide and other acid gases and vapors.

Type K for use against ammonia and organic ammonia derivatives

Class P1 intended for use against mechanically generated particulates of sizes most commonly encountered in industry, e.g. asbestos, silica.

Class P2 intended for use against both mechanically and thermally generated particulates, e.g. metal fume.

Class P3 intended for use against all particulates containing highly toxic materials, e.g. beryllium.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.

Use appropriate NIOSH-certified respirator based on informed professional judgement. In conditions where no reasonable estimate of exposure can be made, assume the exposure is in a concentration IDLH and use NIOSH-certified full face pressure demand SCBA with a minimum service life of 30 minutes, or a combination full facepiece pressure demand SAR with auxiliary self-contained air supply. Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

#### **ENGINEERING CONTROLS**

Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapors, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100 -200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion) Within each range the appropriate value depends on:	1-2.5 m/s (200 -500 f/min.)
Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200 - 500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

# **Section 9 - PHYSICAL AND CHEMICAL PROPERTIES**

## PHYSICAL PROPERTIES

Solid. Mixes with water.			
State	Divided solid	Molecular Weight	1066.2
Melting Range (°F)	Heat labile	Viscosity	Not available
Boiling Range (°F)	Not applicable	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	4-9
Decomposition Temp (°F)	Not available.	pH (as supplied)	Not applicable

Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not available
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

#### APPEARANCE

Odourless powder. Mixes with water.

# **Section 10 - CHEMICAL STABILITY**

# CONDITIONS CONTRIBUTING TO INSTABILITY

- .
  - Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerization will not occur.

## STORAGE INCOMPATIBILITY

Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

# Section 11 - TOXICOLOGICAL INFORMATION

#### tylosin tartrate

# TOXICITY AND IRRITATION

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY Oral (rat) LD50: >6200 mg/kg

Intravenous (rat) LD50: 695 mg/kg

Oral (mouse) LD50: >6200 mg/kg

Subcutaneous (mouse) LD50: 1354 mg/kg

Intravenous (mouse) LD50: 589 mg/kg

Oral (g.pig) LD50: >1000 mg/kg

Oral (chicken) LD50: 5400 mg/kg

Subcutaneous (chicken) LD50: 620 mg/kg

Intravenous (chicken) LD50: 48 mg/kg

Intramscular (chicken) LD50: 432 mg/kg

• Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's edema. The pathogenesis of contact eczema involves a cell -mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitization potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitizing substance which is widely distributed can be a more important allergen than one with stronger sensitizing potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.

Somnolence, convulsions, irritability recorded.

\* Elanco

# Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows: TYLOSIN TARTRATE:

■ Very toxic to aquatic organisms.

■ For tylosin:

Not to be used in laying birds producing eggs for human consumption.

Withholding period: do not administer later than two days for chickens and five days for turkeys before slaughter for human consumption.

Environmental fate:

The environmental photochemical kinetics of tylosin, were investigated under simulated sunlight. An efficient, reversible photoisomerisation was characterised. The activity of the isomer for the inhibition of Escherichia coli DH5a growth was observed to be less than that of tylosin. On a longer time scale than that of isomerisation, the isomer mixture undergoes photolysis. Indirect photosensitisation was not a significant loss process

Tylosin is a macrolide antibiotic, which consists of four factors (A, B, C, D). Tylosin A is degraded with a half-life of 200 d in the light in water, and the total loss of tylosin A in the dark is 6% of the initial spiked amount during the experimental period. Tylosin C and D are relatively stable except in ultrapure water in the light. Slight increases of tylosin B after two months and formation of two photoreaction isomers of tylosin A were observed under exposure to light. However, tylosin probably would degrade faster if the experimental containers did not prevent ultraviolet transmission. In soil, tylosin A has a dissipation half -life of 7 d, and tylosin D is slightly more stable, with a dissipation half-life of 8 d in unsterilised and sterilized soil. Sorption and

IRRITATION Eye (rabbit): irritating \* Skin (rabbit): non-irritating \*

abiotic degradation are the major factors influencing the loss of tylosin in the environment, and no biotic degradation was observed at the test concentration either in pond water or in an agronomic soil, as determined by comparing dissipation profiles in sterilized and unsterilised conditions for tylosin base log Kow: 1.7 Water solubility (g/l): 5 Light absorption in ethanol (nm): 282 Soil degradation half-life (days): 62 for tylosin factor A; 37 for tylosin factor D Ecotoxicity: for tylosin base: Fish LC50 (96 h): rainbow trout, bluegill >300 mg/l described as median lethal concentration (Elanco) Daphnia magna EC50 (48 h) >300 mg/l Bird 14-day oral LC50: bobwhite quail >5000 ppm Bird 5-day dietary LC50: mallard duck >5000 ppm Earthworm LC50 (28-day): >102.6 mg/kg Alga EC50 (0.22 mg/l): P. subspicatus 0.22 mg/l (growth) Seedling EC50: tomato 43 mg/kg; soybean 53 mg/kg; oat 140 mg/kg Environmental summary: Practically non-toxic to fish, birds, earthworms and aquatic invertebrates. Highly toxic to algae. No volatility expected. Not expected to bioconcentrate in aquatic organisms. Low mobility in soil. Not persistent in the environment due to degradation and possible photolysis. Lily Aquatic Exposure Guideline (LAEG): for tylosin base LAEG for drinking water: 36 ug/l LAEG for chronic exposure of aquatic organisms: 2500 ug/l LAEG for acute exposure of aquatic organisms: 5000 ug/l.

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not

contaminate water when cleaning equipment or disposing of equipment wash-waters. Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

DO NOT discharge into sewer or waterways.

# Section 13 - DISPOSAL CONSIDERATIONS

#### **Disposal Instructions**

All waste must be handled in accordance with local, state and federal regulations.

Puncture containers to prevent re-use and bury at an authorized landfill.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: Burial in a licensed land-fill or Incineration in a licensed apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

# **Section 14 - TRANSPORTATION INFORMATION**



8011			
Symbols:	G	Hazard class or Division:	9
Identification Numbers:	UN3077	PG:	III
Label Codes:	9	Special provisions:	8, 146, 335, B54, IB8, IP3, N20, T1, TP33
Packaging: Exceptions:	155	Packaging: Non-bulk:	213
Packaging: Exceptions:	155	Quantity limitations: Passenger aircraft/rail:	No limit
Quantity Limitations: Cargo aircraft only:	No limit	Vessel stowage: Location:	A

Vessel stowage: Other: None

Hazardous materials descriptions and proper shipping names:

# Environmentally hazardous substance, solid, n.o.s Air Transport IATA:

ICAO/IATA Class:	9	ICAO/IATA Subrisk:	殇—	
UN/ID Number:	3077	Packing Group:	III	
Special provisions:	A97			
Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. *(CONTAINS TYLOSIN TARTRATE) Maritime Transport IMDG:				

IMDG Class:	9	IMDG Subrisk:	None
UN Number:	3077	Packing Group:	III
EMS Number:	F -A,S-F	Special provisions:	274 909 944

Limited Quantities: 5 kg

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains tylosin tartrate)

# Section 15 - REGULATORY INFORMATION

## tylosin tartrate (CAS: 74610-55-2,1405-54-5) is found on the following regulatory lists;

"OECD Representative List of High Production Volume (HPV) Chemicals"

# **Section 16 - OTHER INFORMATION**

## LIMITED EVIDENCE

- Ingestion may produce health damage\*.
- Cumulative effects may result following exposure\*.
- Possible respiratory sensitizer\*.
- Exposure may produce irreversible effects\*.
- \* (limited evidence).

#### Ingredients with multiple CAS Nos

Ingredient Name tylosin tartrate

CAS 74610-55-2, 1405-54-5

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 Classification of the mixture and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
 A list of reference resources used to assist the committee may be found at: www.chemwatch.net/references.

• The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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