Elanco

SAFETY DATA SHEET

1. Identification

Product identifier

Tylan Sulfa-G Premix

Other means of identification

Item Code

AF0901, AF0902, AF0903, AF0904, AF0905, AF0909, AF0912, AF0928, MS8271

Synonyms

Tylosin, phosphate (salt) * Benzenesulfonamide, 4-amino-N-(4,6-dimethyl-2-pyrimidinyl)- * Tylosir Phosphate Formulation * Sulfamethazine Formulation * Sulphadimidine Formulation * Tylasul

Premix * Tylan Plus Sulfa Premix

Recommended use

Veterinary Product

Recommended restrictions

None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company Name

Elanco Animal Health

2500 Innovation Way Greenfield, IN 46140

US

Phone:

1-877-Elanco1 (1-877-352-6261)

Email:

lilly_msds@lilly.com

Emergency Telephone

Numbers:

Elanco Product Technical Support / Human or Animal Exposure Reporting:

1-888-545-5973

Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300

(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards

Not classified.

Health hazards

Serious eye damage/eye irritation

Category 2A

Sensitization, respiratory

Category 1

Sensitization, skin

Category 1

Reproductive toxicity

Effects on or via lactation

OSHA defined hazards

Combustible dust

Label elements



Signal word

Danger

Hazard statement

May form combustible dust concentrations in air.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H362 May cause harm to breast-fed children.

Precautionary statement

Prevention

P201 Obtain special instructions before use.

P263 Avoid contact during pregnancy/while nursing.
P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P285 In case of inadequate ventilation wear respiratory protection.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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Response

P304 + P340

IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

P302 + P352 P308 + P313 IF ON SKIN: Wash with plenty of soap and water.

IF exposed or concerned: Get medical advice/attention.

Storage

Not available.

Disposal

P501

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

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information

None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	<u>%</u>
Tylosin Phosphate		1405-53 -4	1.8 - 12
Sulfamethazine		57-68-1	1.8 - 12
Excipient: Grain Dust		NA	72 - 85
Anti-dusting oil	MINERAL OIL	8012-95-1	0 - 3

Composition comments

Excipients may include: Soybean feed. Soybean mill run. Rice hulls. Limestone.

The anti-dusting oil reduces potential exposure under normal handling conditions of use.

4. First-aid measures

Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control center **Inhalation**

immediately.

Wash off immediately with soap and plenty of water. Take off contaminated clothing and wash Skin contact

before reuse. Get medical attention if irritation develops and persists.

In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under Eye contact

the eyelids, for at least 15 minutes. Get medical attention immediately.

Rinse mouth thoroughly. Never give anything by mouth to a victim who is unconscious or is having **Ingestion**

convulsions. Call a physician or poison control center immediately.

Most important

symptoms/effects, acute and

delayed

May cause allergic respiratory and skin reactions. Rash. Itching. Hives. Coughing. Shortness of

breath. Watery eyes. Wheezing. May cause harm to breastfed babies.

Indication of immediate medical attention and special

treatment needed

None known.

General information

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. Fire-fighting measures

Suitable extinguishing media

Water, Carbon dioxide (CO2). Dry chemical. Foam.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

Fire or excessive heat may produce hazardous decomposition products.

Special protective equipment

and precautions for firefighters

Wear self-contained breathing apparatus and protective clothing.

General fire hazards Dust may form explosive mixture with air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.

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SDS US

Methods and materials for containment and cleaning up Small Spillages:

Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

Large Spillages:

Prevent further migration into the environment. Remove sources of ignition. Collect in a non-combustible container for prompt disposal. Local authorities should be advised if significant spillages cannot be contained. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance,

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Minimize dust generation and accumulation. Keep away from heat and sources of ignition. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures. Avoid contact with oxidizing agents. Do not store in open or unlabelled containers.

8. Exposure controls/personal protection

Exposure guidelines

Lilly Exposure Guideline (LEG): <100 mcg/m3 12 hour TWA (Tylosin Base) Lilly Exposure Guideline (LEG): <100 mcg/m3 12 hour TWA (Sulfamethazine)

Occupational exposure limits ACCTU

ACGIH Components	Туре	Value	Form
Excipient: Grain Dust (CAS NA)	TWA	4 mg/m3	(grain dust)
US. ACGIH Threshold Limi	t Values		
Components	Туре	Value	Form
Anti-dusting oil (CAS 8012-95-1)	TWA	5 mg/m3	Inhalable fraction.
U.S OSHA			
Components	Туре	Value	Form
Excipient: Grain Dust (CAS NA)	TWA	10 mg/m3	(grain dust)
	for Air Contaminants (29 CFR 1910.1000)		
Components	Туре	Value	Form
Anti-dusting oil (CAS 8012-95-1)	PEL	5 mg/m3	Mist.
US. NIOSH: Pocket Guide 1	to Chemical Hazards		
Components	Туре	Value	Form
Anti-dusting oil (CAS 8012-95-1)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
raical limit values	No biological exposure limits noted for the increa		

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear goggles/face shield.

Skin protection

Other

Hand protection

Chemical-resistant gloves and impermeable body covering to minimize skin contact. Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection

Use an approved respirator. Select appropriate respirator for physical characteristics of material.

Select respirator with appropriate protection factor.

Thermal hazards

Not available.

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General hygiene considerations

Use good industrial hygiene practices in handling this material.

In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling.

When mixing and handling, use protective clothing, impervious gloves, and dust respirator (recommended). Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with plenty of water.

9. Physical and chemical properties

Appearance

Physical state

Solid.

Form

Meal.

Color

Light yellow or Tan.

Odor

Musty

Odor threshold

No data available.

pН

No data available.

Melting point/freezing point

No data available.

Initial boiling point and

No data available.

boiling range

No data available.

Flash point **Evaporation rate** Flammability (solid, gas)

No data available. No test data available.

Upper/lower flammability or explosive limits

Flammability limit - lower No data available.

(%)

Flammability limit -

upper (%)

No data available.

Explosive limit - lower

(%)

No data available.

Explosive limit - upper

(%)

No data available.

No data available. Vapor pressure No data available. Vapor density No data available. Relative density

Solubility(ies)

Solubility (water)

Insoluble.

Partition coefficient

No data available.

(n-octanol/water) **Auto-ignition temperature**

No data available. No data available.

Decomposition temperature

No data available.

Other information

Viscosity

No data available. **Density Explosive properties** Not explosive.

No oxidizing properties. Oxidizing properties

10. Stability and reactivity

Not available. Reactivity Not available. Chemical stability

Material name: Tylan Sulfa-G Premix

Possibility of hazardous

reactions

Will not occur.

Conditions to avoid

Not available.

Incompatible materials

Hazardous decomposition

None known.

products

Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

Product	Species	Test Results
Tylan Sulfa-G Premix (CAS	Mixture)	
Acute		
Dermal		
LD	Rabbit	> 2000 mg/kg (Tylosin-sulfamethazine mixture; no deaths)
Inhalation		
LC50	Rat	> 1000 mg/m3, 1 h (Tylosin-sulfamethazine mixture; no deaths)
Oral		
LD	Rat	> 500 mg/kg (Tylosin-sulfamethazine mixture; no deaths or toxicity)
Components	Species	Test Results
Sulfamethazine (CAS 57-68-	-1)	
Acute		
Dermal		
LD	Rabbit	> 2000 mg/kg (26% formulation)
Inhalation		
	Rat	> 8.4 mg/l, 1 h (26% formulation)
Oral		
LD	Rat	> 500 mg/kg (26% formulation)
Tylosin Phosphate (CAS 140	5-53-4)	way is (1000 to initial conty)
Acute	•	
Dermal		
LD	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 2060 mg/m3, 1 h
Oral		- Lood ing/ind/ 1 II
LD	Rat	> 5000 mg/kg
Other		, 5555 mg/ng
LD50	Mouse	321 mg/kg (Intravenous) Tremors.
	Rat	
	1 1646	600 mg/kg (Intravenous)

Skin corrosion/irritation

Rabbit: Slight irritation. (Tylosin-sulfamethazine mixture)

Serious eye damage/eye

irritation

Rabbit: Irritating. (Tylosin-sulfamethazine mixture)

Respiratory or skin sensitization

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization

May cause an allergic skin reaction.

Germ cell mutagenicity

Mutagenic in one mammalian test system. Not mutagenic in bacterial cell tests and other

mammalian cell tests. Unlikely to pose a genotoxic risk to man. (Tylosin Base)

Negative (Sulfamethazine)

Material name: Tylan Sulfa-G Premix

Carcinogenicity

Animal testing did not show any carcinogenic effects. (Tylosin Base) Remaining ingredients: Not listed by ACGIH, NIOSH, NTP or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Anti-dusting oil (CAS 8012-95-1)

3 Not classifiable as to carcinogenicity to humans.

Sulfamethazine (CAS 57-68-1)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

No effects identified in animal studies. (Tylosin Base)

Decreased offspring survival and fetal changes at doses toxic to the mother. A continuous breeding study reported reduced fertility in mice, but no changes in sperm parameters. May cause harm to

breastfed babies. (Sulfamethazine)

Specific target organ toxicity

- single exposure

Due to lack of data the classification is not possible.

No effects identified in animal studies. (Tylosin Base)

Specific target organ toxicity repeated exposure

Thyroid gland effects. (Sulfamethazine)

Aspiration hazard

No aspiration toxicity classification

Further information

Salivation, diarrhea, and vomiting after repeated large oral doses. (Tylosin Base)

12. Ecological information

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Sulfamethazine (CAS	57-68-1)		
Aquatic			
Chronic			
Fish	NOEC	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	1000 mg/l
Tylosin Base (CAS 140	01-69-0)		
Acute			
	EC50		140 mg/kg (Oats, seedling)
			53 mg/kg (Soybean, seedling)
			43 mg/kg (Tomato, seedling)
	LC50		> 102.6 mg/kg, 14 days (Eisenia fetida earthworm)
Other	EC50	Pseudokirchnerella subcapitata	0.22 mg/l, 72 hours (green algae) (average specific growth rate)
	LC50	Duck	> 5000 mg/kg, 5 days (Anas platyrhynchos, Mallard) (Dietary)
		Quail	> 5000 mg/kg, 5 days (Bobwhite) (Dietary)
			> 2000 mg/kg, 14 days (Bobwhite)
Aquatic Acute			
Crustacea	EC50	Daphnia magna	> 300 mg/l, 48 hours (Water flea)
Fish	LC50	Bluegill (Lepomis macrochirus)	> 300 mg/l, 96 hours
. 16/17		Rainbow Trout	> 300 mg/l, 96 hours (Oncorhynchus mykiss)

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Partition coefficient n-octanol / water (log Kow)

Tylosin Base

17 (pH 7 and 9)

5 (pH 5)

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SDS US 4685 Version #: 01 Issue date: 08-21-2014

Mobility in soil

Soil degradation half-life (100 ppm): 62 days (tylosin factor A); 37 days (tylosin factor D)

Soil degradation half-life (1 mg/kg; 4 soils): 50.3 to 105 days

Leaching in soil column: none

Other adverse effects

Not available.

Ecotoxicological Properties

Drinking Water

Components **Test Results** Tylosin Base 36 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components **Test Results**

Tylosin Base 99 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components **Test Results**

Tylosin Base 220 µg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations

Disposal instructions

Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

UN number UN3077

UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (Tylosin Phosphate)

Transport hazard class(es)

Class 9

Subsidiary risk **Packing group** III

Environmental hazards Yes **ERG Code**

Special precautions for

9L Not available.

user

Other information

Passenger and cargo

aircraft

Allowed.

Cargo aircraft only

Allowed.

IMDG

UN number

UN3077

UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin Phosphate)

Transport hazard class(es)

Class

9

Subsidiary risk

Packing group

Ш

Environmental hazards

Marine pollutant

Yes

EmS

F-A, S-F

Special precautions for Not available.

Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk according to This substance/mixture is not intended to be transported in bulk.

Material name: Tylan Sulfa-G Premix

IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

US state regulations

US. Massachusetts RTK - Substance List

Anti-dusting oil (CAS 8012-95-1)

US. New Jersey Worker and Community Right-to-Know Act

Anti-dusting oil (CAS 8012-95-1)

US. Pennsylvania Worker and Community Right-to-Know Law

Anti-dusting oil (CAS 8012-95-1)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

No *A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing

16. Other information, including date of preparation or last revision

Issue date 08-21-2014

Version # 01

Liffy Lab Code Health: 2 Fire: 1

Reactivity: 0 Special 1: A

List of abbreviations

LEG = Lilly Exposure Guideline

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health 00+1+317-276-2000 00+1-800-428-4441

Revision Information

Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties Toxicological Information: Toxicological Data Ecological Information: Ecotox Property Data

Transport Information: Material Transportation Information

Regulatory Information: Risk Phrases - Class.

GHS: Classification

Material name: Tylan Sulfa-G Premix

