SAFETY DATA SHEET

1. Identification

Product identifier Tylan Premix

Other means of identification

AF0010, AF0024, AF0026, AF0040, AF0042, AF0050, AF0055, AF0080, AF0090, AF0091, AF0099, **Item Code**

AF0105, AH0042, MS8272, MS8274, MS8275, UC5318

Tylosin Premix * Tylosin Phosphate Premix * Tylan 10 Premix * Tylan 30 Premix * Tylan 40 Premix **Synonyms**

* Tylan 50 Premix * Tylan 80 Premix * Tylan * Tylan 100 * Tylan

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

OSHA defined hazards Combustible dust

Label elements



Signal word Danger

Hazard statement

May form combustible dust concentrations in air.

May cause an allergic skin reaction. H317 Causes serious eye irritation. H319

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

Precautionary statement

Prevention

Wear protective gloves/eye protection/face protection. P280 Avoid breathing dust/fume/gas/mist/vapors/spray. P261

In case of inadequate ventilation wear respiratory protection. P285

Response

P304 + P340 IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P342 + P311

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

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SDS US

Not available. **Storage**

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations. P501

Hazard(s) not otherwise

Supplemental information

None known.

classified (HNOC)

None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Tylosin Phosphate		1405-53-4	1.7 - 24
Excipient: Grain Dust		NA	75 - 95
Anti-dusting oil	MINERAL OIL (HIGHLY REFINED) MINERAL OIL	8012-95-1	1 - 2
Other components below reportable levels		< 1	

CLP: Regulation No. 1272/2008. DSD: Directive 67/548/EEC.

Composition comments The full text for all R- and H-phrases is displayed in section 16.

Excipients may include: Corn cob grits. Rice hulls.

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

Shortness of breath. Coughing. Rash. May cause allergic respiratory and skin reactions. Watery

4. First-aid measures

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

immediately.

eyes. Wheezing.

Skin contact Take off contaminated clothing and wash before reuse. Wash off immediately with soap and plenty

of water. 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.

Ingestion Call a physician or poison control center immediately. Never give anything by mouth to a victim

who is unconscious or is having convulsions.

Most important symptoms/effects, acute and

delayed

Indication of immediate

medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. None known.

Water fog. Dry chemical. Foam. Dry chemical powder. Carbon dioxide (CO2).

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to

protect themselves. IF exposed or concerned: Get medical advice/attention.

5. Fire-fighting measures

Suitable extinguishing media

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. Self-contained breathing

apparatus and full protective clothing must be worn in case of fire.

Fire-fighting equipment/instructions In the event of fire, cool tanks with water spray.

General fire hazards

No unusual fire or explosion hazards noted. Dust may form explosive mixture with air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. For personal protection, see section 8 of the SDS. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

Material name: Tylan Premix SDS US 2/9 Methods and materials for containment and cleaning up 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. Collect in a non-combustible container for prompt disposal. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance. Local authorities should be advised if significant spillages cannot be contained. Should not be released into the environment.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep away from heat and sources of ignition. Minimize dust generation and accumulation. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash hands thoroughly after handling. Avoid release to the environment. Avoid contact with eyes, skin, and clothing.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep container tightly closed. Store in a cool, dry place out of direct sunlight. 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)

Occupational exposure limits

-	COTIL	
Δ	((- I H	

Components	Туре	Value	Form
Excipient: Grain Dust (CAS NA)	TWA	4 mg/m3	(grain dust)
US. ACGIH Threshold Limit Valu	ies		
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)
US. OSHA Table Z-1 Limits for A	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 to Ch	emical Hazards		
Components	Туре	Value	Form
Anti-dusting oil (CAS 8012-95-1)	STEL	10 mg/m3	Mist.
,	TWA	5 mg/m3	Mist.

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 safety glasses with side shields (or goggles). Wear goggles/face shield.

Skin protection

Hand protection Wear protective gloves. Chemical-resistant gloves and impermeable body covering to minimize skin

contact.

Other Wear appropriate chemical resistant clothing. Chemical-resistant gloves and impermeable body

covering to minimize skin contact.

Respiratory protection

Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

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Thermal hazards

General hygiene considerations

Wear appropriate thermal protective clothing, when necessary.

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. 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 Granular.
Physical state Solid.
Form Solid.
Color Light tan.
Odor Musty

Odor threshold

PH

No data available.

Melting point/freezing point

No data available.

No data available.

No data available.

boiling range

Flash point

No data available.

Evaporation rate

No data available.

Flammability (solid, gas)

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.

Vapor pressureNo data available.Vapor densityNo data available.Relative densityNo data available.

Solubility(ies)

Solubility (water) Insoluble

Partition coefficient No data available.

(n-octanol/water)

Auto-ignition temperature No data available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

DensityNo data available.Explosive propertiesNo data available.Oxidizing propertiesNo oxidizing properties.

Material name: Tylan Premix SDS US

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

Will not occur.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Tylosin Base (CAS 1401-69-0)		
Acute		
Dermal		
LD	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 2060 mg/m3, 1 h
Oral		
LD	Rat	> 5000 mg/kg
Other		
LD50	Mouse	321 mg/kg (Intravenous) Tremors.
	Rat	600 mg/kg (Intravenous)
Skin corrosion/irritation	Rabbit: No irritation (22% Tylo	osin phosphate mixture)

2% Tylosiii pilospilate ii

Serious eye damage/eye

irritation

Causes eye irritation. Rabbit: (22% Tylosin phosphate mixture)

Respiratory or skin sensitization

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

Skin sensitization Guinea pig: Causes sensitization. (Tylosin Base)

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)

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Not listed by Carcinogenicity

ACGIH, IARC, NIOSH, NTP OR OSHA. (Tylosin phosphate)

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity No effects identified in animal studies. (Tylosin Base)

Specific target organ toxicity

- single exposure

Not available.

Specific target organ toxicity

- repeated exposure

No effects identified in animal studies. (Tylosin Base)

Aspiration hazard No aspiration toxicity classification

Chronic effects Causes damage to organs through prolonged or repeated exposure.

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.

Material name: Tylan Premix SDS US

Components		Species	Test Results
Tylosin Base (CAS 140	1-69-0)		
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 <i>Acute</i>			
Crustacea	EC50	Daphnia magna	> 300 mg/l, 48 hours (Water flea)
Fish	LC50	Bluegill (Lepomis macrochirus)	> 300 mg/l, 96 hours
		Rainbow Trout	> 300 mg/l, 96 hours (Oncorhynchus mykiss)

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

Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)

Tylosin Base 17 (pH 7 and 9)

5 (pH 5)

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 effectsNo other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

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. Confirm disposal procedures with

environmental engineer and local 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)

Material name: Tylan Premix

Transport hazard class(es)

9 Class Subsidiary risk **Packing group** III**Environmental hazards** Yes **ERG Code** 91

Special precautions for

user

Not available.

Other information

Passenger and cargo Allowed. aircraft Cargo aircraft only

Allowed.

IMDG

UN3077 **UN** number

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**

Marine pollutant Yes F-A, S-F **EmS** 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.

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)

SARA 304 Emergency release notification

Not regulated.

Material name: Tylan Premix SDS US

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 - No 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

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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

Issue date 06-26-2014

Version # 01

Lilly Lab Code Health: 2

Fire: 1 Reactivity: 0 Special 1: A

List of abbreviations LEG = Lilly Exposure Guideline

Material name: Tylan Premix sps us

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 country(s).

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 Exposure Controls / Personal Protection: OELs Physical & Chemical Properties: Multiple Properties

Ecological Information: Ecotoxicity

Transport Information: Proper Shipping Name/Packing Group

Regulatory Information: Risk Phrases - Labeling

Toxicological Information: Toxicological Data

GHS: Classification

Material name: Tylan Premix SDS US

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