



# Tylan Sulfa-G Premix

Effective Date: 16-Dec-2004

**Elanco Animal Health**  
**Material Safety Data Sheet**

## Section 1 - Chemical Product and Company

**Manufacturer:**

Elanco Animal Health  
 Division of Eli Lilly and Company  
 2001 West Main St  
 PO Box 708  
 Greenfield, IN 46140

**Manufacturer's Emergency Phone:**

1-800-428-4441

**CHEMTREC:**

1-800-424-9300 (North America)

1-703-527-3887 (International)

**Common Name:** Tylan Sulfa-G Premix

**Chemical Name:** Tylosin, phosphate (salt)

**Chemical Name 2:** Benzenesulfonamide, 4-amino-N-(4,6-dimethyl-2-pyrimidinyl)-

**Synonym(s):** Tylosin Phosphate Formulation; Sulfamethazine Formulation; Sulphadimidine Formulation

**Trademarks(s):** Tylasul Premix; Tylan Plus Sulfa Premix

**Lilly Item Code(s):** AF0901; AF0902; AF0903; AF0904; AF0905; AF0909; AF0912; AF0928; MS8271

See attached glossary for abbreviations.

## Section 2 - Composition / Information on Ingredients

<b>Ingredient</b>	<b>CAS</b>	<b>Concentration %</b>
Tylosin Phosphate	1405-53-4	1.8 - 12
Sulfamethazine	57-68-1	1.8 - 12
Excipients	NA	72 - 85
Anti-dusting Oil	NAIF	0 - 3

Excipients may include soybean feed, soybean mill run, starch, rice hulls, or limestone.

**Exposure Guidelines:** Tylosin phosphate - LEG <100 micrograms/m<sup>3</sup> TWA for 12 hours.

Sulfamethazine - LEG <100 micrograms/m<sup>3</sup> TWA for 12 hours.

Grain dust - PEL 10 mg/m<sup>3</sup> TWA. TLV 4 mg/m<sup>3</sup> TWA for 8 or 12 hours (total). Lilly preferred

exposure limit is TLV.

UK - Maximum Exposure Limit 10 mg/m<sup>3</sup> TWA (total) (Sens).

Ireland - Occupational Exposure Limit 10 mg/m<sup>3</sup> TWA (Sens).

Limestone dust - PEL 5 mg/m<sup>3</sup> TWA (respirable) and 15 mg/m<sup>3</sup> TWA (total). TLV 10 mg/m<sup>3</sup> TWA.

UK - Exposure Standard 4 mg/m<sup>3</sup> TWA (respirable) and 10 mg/m<sup>3</sup> TWA (total).

Ireland - Occupational Exposure Limit 4 mg/m<sup>3</sup> TWA (respirable) and 10 mg/m<sup>3</sup> TWA (total).

France - Occupational Exposure Limit 10 mg/m<sup>3</sup> (VME) TWA.

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

## Section 3 - Hazards Identification

**Appearance:** Light tan to straw-colored meal

**Physical State:** Solid

**Odor:** Musty

<h3>Emergency Overview</h3>			
<p><b>Emergency Overview Effective Date:</b> 27-Nov-2001</p>		<p>Special A = Allergen</p>	
<p><b>Lilly Laboratory Labeling Codes:</b></p>			
<p><b>Health 2</b></p>	<p><b>Fire 1</b></p>	<p><b>Reactivity 0</b></p>	<p><b>Special A</b></p>
<p><b>Primary Physical and Health Hazards:</b> Irritant (eyes). Severe Allergen.</p>			
<p><b>Caution Statement:</b> Tylan Sulfa-G Premix contains tylosin phosphate and sulfamethazine, may be irritating to the eyes, and is classified as a severe allergen because repeated unprotected exposures are likely to cause allergic reactions.</p>			

**Routes of Entry:** Inhalation and skin contact.

**Effects of Overexposure:** Allergic reactions to tylosin and sulfamethazine in a manufacturing setting have been reported. Allergy symptoms may include skin rash, itching, hives, watery eyes, shortness of breath, nasal congestion, coughing, and wheezing. Based on animal data for mixture of both materials, may be irritating to the eyes.

Excipients - Prolonged exposure to high concentrations of grain dust may cause irritation of the respiratory tract and mucous membranes.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to tylosin or sulfonamides.

**Carcinogenicity:** Tylosin base - Not listed by IARC, NTP, ACGIH, or OSHA. Not considered

carcinogenic in animal studies conducted by Lilly Research Laboratories.

Sulfamethazine - IARC Group 3 (not classifiable as to human carcinogenicity). Not listed by NTP, ACGIH, or OSHA.

## Section 4 - First Aid Measures

**Eyes:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

**Skin:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

**Inhalation:** Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

**Ingestion:** Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

## Section 5 - Fire Fighting Measures

**Flash Point:** No applicable information found

**UEL:** No applicable information found

**LEL:** No applicable information found

**Extinguishing Media:** Use water, carbon dioxide, dry chemical, foam, or Halon.

**Unusual Fire and Explosion Hazards:** As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

**Hazardous Combustion Products:** May emit toxic fumes when exposed to heat or fire.

## Section 6 - Accidental Release Measures

**Spills:** Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping.

## Section 7 - Handling and Storage

**Storage Conditions:** Store in a cool, dry place. Protect from moisture and heat. Product should not be used after the date printed on the container.

## Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

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

**Respiratory Protection:** Use an approved respirator.

**Eye Protection:** Chemical goggles and/or face shield.

**Ventilation:** Laboratory fume hood or local exhaust ventilation.

**Other Protective Equipment:** 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.

**Additional Exposure Precautions:** In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs. 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.

## Section 9 - Physical and Chemical Properties

**Appearance:** Light tan to straw-colored meal

**Odor:** Musty

**Boiling Point:** No applicable information found

**Melting Point:** No applicable information found

**Specific Gravity:** No applicable information found

**pH:** No applicable information found

**Evaporation Rate:** No applicable information found

**Water Solubility:** Insoluble

**Vapor Density:** No applicable information found

**Vapor Pressure:** No applicable information found

## Section 10 - Stability and Reactivity

**Stability:** Stable at normal temperatures and pressures.

**Incompatibility:** May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

**Hazardous Decomposition:** May emit toxic fumes when heated to decomposition.

**Hazardous Polymerization:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

No data are available for Tylan Sulfa-G Premix. Toxicity data for a tylosin-sulfamethazine mixture are presented.

**Oral:** Tylosin-sulfamethazine mixture - Rat, 500 mg/kg, no deaths or toxicity.

**Skin:** Tylosin-sulfamethazine mixture - Rabbit, 2000 mg/kg, no deaths.

**Inhalation:** Tylosin-sulfamethazine mixture - Rat, 1000 mg/m<sup>3</sup> for 1 hour, no deaths.

**Skin Contact:** Tylosin-sulfamethazine mixture - Rabbit, slight irritant

**Eye Contact:** Tylosin-sulfamethazine mixture - Rabbit, irritant

### Chronic Exposure

**Target Organ Effects:** Tylosin base - No effects identified in animal studies.  
Sulfamethazine - Thyroid effects (goiter, tissue changes).

**Other Effects:** Tylosin base - Salivation, diarrhea, and vomiting after repeated large oral doses.

**Reproduction:** Tylosin base - No effects identified in animal studies.  
Sulfamethazine - 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

**Sensitization:** Tylosin base - Guinea pig, positive contact sensitizer.

**Mutagenicity:** Tylosin base - Mutagenic in one mammalian test system. Not mutagenic in bacterial cell tests and other mammalian cell tests. Unlikely to pose a genotoxic hazard to man.  
Sulfamethazine - Not mutagenic in bacterial or mammalian cells.

## Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

**Environmental Summary:** Tylosin base - Practically nontoxic 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.

Sulfamethazine - Practically non-toxic to aquatic organisms. If released into air, material is expected to exist primarily in the particulate-phase and may be removed by wet or dry deposition processes. Vapor-phase material is expected to rapidly degrade in the atmosphere. Material may covalently bond with humic materials in soil and water. Material not covalently bonded may leach into

groundwater. Volatilization is not expected to occur. Material is not expected to bioconcentrate in aquatic organisms.

**Lilly Aquatic Exposure Guideline (LAEG):** Tylosin base

LAEG for Drinking Water: 36 micrograms/L

LAEG for Chronic Exposure of Aquatic Organisms: 99 micrograms/L

LAEG for Acute Exposure of Aquatic Organisms: 220 micrograms/L

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

**Container Disposal:** Packages may be burned or buried in accordance with environmental standards.

## Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Elanco Animal Health usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

### U.S. Regulations

Tylosin phosphate

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Sulfamethazine

TSCA - Yes

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

## EU Regulations

### EC Classification

Xn (Harmful)

Xi (Irritant)

### Risk Phrases

R 36 - Irritating to eyes.

R 42/43 - May cause sensitization by inhalation and skin contact.

### Safety Phrases

S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

## Section 16 - Other Information

**MSDS Sections Revised:** Section 12.

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 MERCHANTABILITY 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

1-800-428-4441

1-317-276-2000

### GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

CHAN = Chemical Hazard Alert Notice

CHEMTREC = Chemical Transportation Emergency Center

DOT = Department of Transportation

EC = European Community

EINECS = European Inventory of Existing Chemical Substances

ELINCS = European List of New Chemical Substances

EPA = Environmental Protection Agency

HEPA = High Efficiency Particulate Air (Filter)

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/International Air Transport Association

IEG = Lilly Interim Exposure Guideline  
IMO = International Maritime Organization  
Kow = Octanol/Water Partition Coefficient  
LEG = Lilly Exposure Guideline  
LEL = Lower Explosive Limit  
MSDS = Material Safety Data Sheet  
MSHA = Mine Safety and Health Administration  
NA = Not Applicable, except in Section 14 where NA = North America  
NADA = New Animal Drug Application  
NAIF = No Applicable Information Found  
NCI = National Cancer Institute  
NIOSH = National Institute for Occupational Safety and Health  
NOS = Not Otherwise Specified  
NTP = National Toxicology Program  
OSHA = Occupational Safety and Health Administration  
PEL = Permissible Exposure Limit (OSHA)  
RCRA = Resource Conservation and Recovery Act  
RQ = Reportable Quantity  
RTECS = Registry of Toxic Effects of Chemical Substances  
SARA = Superfund Amendments and Reauthorization Act  
STEG = Lilly Short Term Exposure Guideline  
STEL = Short Term Exposure Limit  
TLV = Threshold Limit Value (ACGIH)  
TPQ = Threshold Planning Quantity  
TSCA = Toxic Substances Control Act  
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted  
UEL = Upper Explosive Limit  
UN = United Nations  
WEEL = Workplace Environmental Exposure Level (AIHA)