

SAFETY DATA SHEET

Tylan Soluble

Section 1. Identification

GHS product identifier

: Tylan Soluble

Product code

: 124000000626

Other means of identification

: 4270400; 1405-54-5; AF1298; AF1300; AF1310; AF1317; AF1320; AH0670; Elanco AF1300 Tylan Tylosin Tartrate Soluble; Tylosin, (2R,3R)-2,3-dihydroxybutanedioate

(salt)

Relevant identified uses of the substance or mixture and uses advised against

Identified uses :

: Veterinary pharmaceutical.

Uses advised against

: None known.

Company Name

: Elanco US Inc.

2500 Innovation Way Greenfield IN, US 46140

Telephone number

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

Emergency telephone

: Elanco Product Technical Support / Human or Animal Exposure Reporting:

number

Email

1-888-545-5973

Transportation Emergency

: elanco_sds@elancoah.com: CHEMTREC: 1-800-424-9300

telephone number

(Outside U.S. CHEMTREC International: 00 1-703-527-3887)

Section 2. Hazards identification

OSHA/HCS status

: This material is considered hazardous by the OSHA Hazard Communication Standard

(29 CFR 1910.1200).

Classification of the substance or mixture

: COMBUSTIBLE DUSTS

EYE IRRITATION - Category 2B

RESPIRATORY SENSITIZATION - Category 1

SKIN SENSITIZATION - Category 1

GHS label elements

Hazard pictograms



Signal word

: Danger

Hazard statements

: H317 - May cause an allergic skin reaction.

H320 - Causes eye irritation.

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

May form combustible dust concentrations in air.

Precautionary statements

Prevention

: P280 - Wear protective gloves.

P284 - Wear respiratory protection.
P261 - Avoid breathing dust or mist.
P264 - Wash thoroughly after handling.

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Section 2. Hazards identification

Response

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

P363 - Wash contaminated clothing before reuse. P302 + P352 - IF ON SKIN: Wash with plenty of water.

P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.

Storage Disposal : Not applicable.

: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Supplemental label elements

: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.

Hazards not otherwise classified

: None known.

Section 3. Composition/information on ingredients

Substance/mixture : Substance

Ingredient name	%	CAS number
Tylosin, [R-(R*,R*)]-2,3-dihydroxybutanedioate (salt)	100	1405-54-5

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact

: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. If irritation persists, get medical attention.

Inhalation

: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours. In the event of any complaints or symptoms, avoid further exposure.

Skin contact

Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion

: Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

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Section 4. First aid measures

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : Causes eye irritation.

Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits

may cause irritation of the nose, throat and lungs. May cause allergy or asthma

symptoms or breathing difficulties if inhaled.

Skin contact: May cause an allergic skin reaction.

Ingestion: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact: Adverse symptoms may include the following:

irritation watering redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

wheezing and breathing difficulties

asthma

Skin contact: Adverse symptoms may include the following:

irritation redness

Ingestion: No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician

: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments

Protection of first-aiders

No specific treatment.

: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

: Use dry chemical powder.

Unsuitable extinguishing

media

: Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

Specific hazards arising from the chemical

: May form explosible dust-air mixture if dispersed.

Hazardous thermal decomposition products

: Decomposition products may include the following materials:

carbon dioxide carbon monoxide nitrogen oxides

Special protective actions for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders:

If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill

: Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill

: Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures

: Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems or asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene

: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

: Do not store above the following temperature: 95°C (203°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

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Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Tylosin, [R-(R*,R*)] -2,3-dihydroxybutanedioate (salt)	None.

Appropriate engineering controls

: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Environmental exposure controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles. If operating conditions cause high dust concentrations to be produced, use dust goggles.

Skin protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Solid. [Powder.]

Color : Yellow.
Odor : Odorless.

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Section 9. Physical and chemical properties and safety characteristics

Odor threshold : Not available.

pН : 4.5 to 7.2 [Conc. (% w/w): 50%]

Melting point/freezing point **Boiling point, initial boiling** point, and boiling range

: 240°C (464°F) : Not available.

Flash point : Not applicable. **Evaporation rate** : Not available. **Flammability** : Not available.

Lower and upper explosion limit/flammability limit

: Not applicable.

Vapor pressure : Not available. Relative vapor density : Not applicable. **Relative density** : Not available. **Solubility** : Not available.

Solubility in water 5 g/l

Partition coefficient: n-

: Not applicable.

octanol/water

Viscosity

: Not applicable. **Auto-ignition temperature Decomposition temperature**

: Not available. : Not applicable.

Flow time (ISO 2431)

: Not available.

Particle characteristics

Median particle size : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid

: Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation.

Incompatible materials

: Reactive or incompatible with the following materials: oxidizing materials

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Tylosin, [R-(R*,R*)] -2,3-dihydroxybutanedioate (salt)	LD50 Dermal	Rabbit	>2000 mg/kg	-
,	LD50 Oral	Rat	>6200 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Tylosin, [R-(R*,R*)] -2,3-dihydroxybutanedioate (salt)	Eyes - Irritant	Rabbit	-	-	-
,	Skin - Mild irritant	Rabbit	-	-	-

Sensitization

Product/ingredient name	Route of exposure	Species	Result
Tylosin, [R-(R*,R*)] -2,3-dihydroxybutanedioate (salt)	skin	Guinea pig	Sensitizing

Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure

: Not available.

Potential acute health effects

Eye contact : Causes eye irritation.

Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits

may cause irritation of the nose, throat and lungs. May cause allergy or asthma

symptoms or breathing difficulties if inhaled.

: May cause an allergic skin reaction. **Skin contact**

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

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Section 11. Toxicological information

Eye contact: Adverse symptoms may include the following:

irritation watering redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

wheezing and breathing difficulties

asthma

Skin contact: Adverse symptoms may include the following:

irritation redness

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate

: Not available.

effects

Potential delayed effects : Not available.

Long term exposure

Potential immediate

: Not available.

effects

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation. Once

sensitized, a severe allergic reaction may occur when subsequently exposed to very low

levels.

Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	(0)	(vapors)	Inhalation (dusts and mists) (mg/ I)
Tylosin, [R-(R*,R*)]-2,3-dihydroxybutanedioate (salt)	N/A	2500	N/A	N/A	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Tylosin, [R-(R*,R*)] -2,3-dihydroxybutanedioate (salt)	Acute EC50 0.22 mg/l	Algae	72 hours
	Acute EC50 >300 mg/l	Daphnia	48 hours
	Acute LC50 >300 mg/l	Fish	96 hours

Persistence and degradability

Not available.

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Section 12. Ecological information

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects

: No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	TDG Classification	Mexico Classification	IMDG	IATA
UN number	Not regulated.	UN3077	UN3077	UN3077	UN3077
UN proper shipping name	-	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin, [R-(R*, R*)] -2,3-dihydroxybutanedioate (salt))	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin, [R-(R*, R*)] -2,3-dihydroxybutanedioate (salt))	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin, [R-(R*, R*)] -2,3-dihydroxybutanedioate (salt))	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin, [R-(R*, R*)] -2,3-dihydroxybutanedioate (salt))
Transport hazard class(es)	-	9	9	9	9
Packing group	-	III	III	III	III
Environmental hazards	No.	Yes.	Yes.	Yes.	Yes.

Additional information

TDG Classification

: Product classified as per the following sections of the Transportation of Dangerous Goods Regulations: 2.43-2.45 (Class 9), 2.7 (Marine pollutant mark). Non-bulk packages of this product are not regulated as dangerous goods when transported by road or rail.

Mexico Classification

: The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg.

IMDG

: This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

IATA

: This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

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Section 14. Transport information

Special precautions for user : Transport within user's premises: always transport in closed containers that are

upright and secure. Ensure that persons transporting the product know what to do in the

event of an accident or spillage.

Transport in bulk according : Not available.

to IMO instruments

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

Clean Air Act Section 112

(b) Hazardous Air **Pollutants (HAPs)** : Not listed

Clean Air Act Section 602

Class I Substances

: Not listed

Clean Air Act Section 602

Class II Substances

: Not listed

DEA List I Chemicals

(Precursor Chemicals)

: Not listed

DEA List II Chemicals

: Not listed

(Essential Chemicals)

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : COMBUSTIBLE DUSTS

EYE IRRITATION - Category 2B

RESPIRATORY SENSITIZATION - Category 1

SKIN SENSITIZATION - Category 1

Composition/information on ingredients

Name	%	Classification
Tylosin, [R-(R*,R*)] -2,3-dihydroxybutanedioate (salt)		EYE IRRITATION - Category 2B RESPIRATORY SENSITIZATION - Category 1 SKIN SENSITIZATION - Category 1

State regulations

Massachusetts : None of the components are listed. **New York** : None of the components are listed. **New Jersey** : None of the components are listed. **Pennsylvania** : None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

Inventory list

United States : Not determined.

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Section 16. Other information

History

Date of issue/Date of

revision

: 8/1/2022

Date of previous issue : 8/1/2022 Version : 0.05

Key to abbreviations : ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973

as modified by the Protocol of 1978. ("Marpol" = marine pollution)

N/A = Not available SGG = Segregation Group UN = United Nations

References : Not available.

Indicates information that has changed from previously issued version.

Notice to reader

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 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 0011+1-877-352-6261 0011+1-800-428-4441

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