



# SECTION 1: IDENTIFICATION

**1.1 Product identifier:** Norbrook Laboratories Ltd - Tulieve Injection for Cattle and Swine - ANDA 200-723

61027

Other means of identification:

Non-applicable

1.2 Recommended use of the chemical and restrictions on use:

Relevant uses (Professional users): Veterinary Pharmaceutical Product Relevant uses (Industrial user): Veterinary Pharmaceutical Product Uses advised against: All uses not specified in this section or in section 7.3

1.3 Name, U.S. address, and U.S. telephone number of the chemical manufacturer, importer, or other responsible party:

Norbrook Laboratories Ltd Carnbane Industrial Estate

BT35 6QQ Newry - Northern Ireland

Phone: +44 (0)28 3026 4435 - Fax: +44 (0)28 3026 5060

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Norbrook, Inc. 9733 Loiret Blvd Lenexa, KS 66219

1.4 Emergency phone number: +44 (0)28 3026 4435 USA Telephone Number 913-599-5777

# SECTION 2: HAZARD(S) IDENTIFICATION

#### 2.1 Classification of the substance or mixture:

#### 29 CFR 1910.1200:

Classification of the chemical in accordance with paragraph (d)(1)(i) of 29 CFR 1910.1200

Eye Irrit. 2A: Eye irritation, Category 2A, H319 Skin Sens. 1: Sensitisation, skin, Category 1, H317

2.2 Label elements:

#### 29 CFR 1910.1200:

Warning



# **Hazard statements:**

Eye Irrit. 2A: H319 - Causes serious eye irritation. Skin Sens. 1: H317 - May cause an allergic skin reaction.

# **Precautionary statements:**

P261: Avoid breathing vapours P264: Wash thoroughly after use.

P280: Wear protective gloves/protective clothing/respiratory protection/eye protection/protective footwear.

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

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P337+P313: If eye irritation persists: Get medical advice/attention.

P501: Dispose of contents and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

# Substances that contribute to the classification

Tulathromycin (CAS: 217500-96-4)

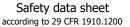
# 2.3 Hazards not otherwise classified (HNOC):

Non-applicable

# SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances:

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# SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Non-applicable

#### 3.2 Mixtures:

Chemical description: Aqueous emulsion

#### Components:

Remaining components are non-hazardous and/or present at amounts below reportable limits. The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of 29 CFR 1910.1200. Therefore, in accordance with Appendix D to 29 CFR 1910.1200, the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 217500-96-4	Tulathromycin	Proprietary
	Eye Irrit. 2A: H319; Skin Sens. 1: H317 - Warning	>
CAS: 77-92-9	Citric Acid	Proprietary
	Eye Irrit. 2A: H319; STOT SE 3: H335 - Warning	>

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

# **SECTION 4: FIRST-AID MEASURES**

#### 4.1 Description of necessary measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

#### By inhalation:

This product is not classified as hazardous through inhalation,however, it is recommended in case of intoxication symptoms to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

#### By skin contact:

May cause an allergic skin reaction. In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes on the skin (stinging, redness, rashes, blisters), seek medical advice with this Safety Data Sheet

#### By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

#### By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS of this product.

# 4.2 Most important symptoms/effects, acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

# SECTION 5: FIRE-FIGHTING MEASURES

# 5.1 Suitable (and unsuitable) extinguishing media:

# Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

# Unsuitable extinguishing media:

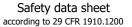
Non-applicable

# 5.2 Specific hazards arising from the chemical:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

#### 5.3 Special protective equipment and precautions for fire-fighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and Self Contained Breathing Apparatus. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)





# SECTION 5: FIRE-FIGHTING MEASURES (continued)

# Additional provisions:

As in any fire, prevent human exposure to fire, smoke, fumes or products of combustion. Only properly trained personnel should be involved in firefighting. Evacuate nonessential personnel from the fire area. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

# SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures:

#### For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

#### For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

#### 6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

#### 6.3 Methods and materials for containment and cleaning up:

For accidental releases in excess of reportables quantities (RQ) (Table 302.4), refer to 40 CFR 302 for detailed instructions concerning reporting requirements and notify the National Response Center (800) 424-8802.

Prevent the entrance of product in drains, sewers or watercourses. Absorb the spill using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. Collect the product in appropriate containers and manage it according to current legislation.

Spillages in water or sea:

Small spillages:

Contain spillage using barriers or similar equipment. Use suitable absorbents for collection and treat the waste in accordance with current regulations.

Large spillages:

If possible, contain spillage in open water using barriers or similar equipment. If this is not possible, try to control its spread and collect the product with suitable mechanical means. Always consult experts before using dispersants and make sure you have the necessary approvals if they are to be used. Treat the waste according to current regulations.

# 6.4 Reference to other sections:

See sections 8 and 13.

# SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

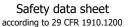
# 7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Maximum Temp.: 77 °F

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5





# SECTION 7: HANDLING AND STORAGE (continued)

#### 7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

# SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 **Control parameters:**

Substances whose occupational exposure limits have to be assessed in the workplace:

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000):

Identification	Occupational exposure limits		
sodium hydroxide	8-hour TWA PEL 2 mg/m <sup>3</sup>		2 mg/m <sup>3</sup>
CAS: 1310-73-2	Ceiling Values - TWA PEL		

#### CALIFORNIA- TABLE AC-1 PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS:

Identification	Occupational exposure limits	
sodium hydroxide	PEL	2 mg/m <sup>3</sup>
CAS: 1310-73-2	STEL	

# NIOSH: Immediately Dangerous To Life or Health (IDLH) Values:

Identification Occupational exposure limits		its	
sodium hydroxide	TWA		
CAS: 1310-73-2	IDLH Value 10 mg/m³		10 mg/m <sup>3</sup>

#### 8.2 **Appropriate engineering controls:**

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protection Equipment. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation, the information on clothing performance must be combined with professional judgment, and a clear understanding of the clothing application, to provide the best protection to the worker. All chemical protective clothing use must be based on a hazard assessment to determine the risks for exposure to chemicals and other hazards. Conduct hazard assessments in accordance with 29 CFR 1910.132.

#### B.- Respiratory protection

Pictogram	PPE	Remarks
Mandatory respiratory tract protection	Filter mask for gases and vapours (Filter type: A)	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment. Use respirator in accordance with manufacturer's use limitations and OSHA standard 1910.134 (29CFR)

# C.- Specific protection for the hands

Pictogram	PPE	Remarks
Mandatory hand protection	Protective gloves against minor risks	Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional /industrial users, we recommend using chemical protection gloves. Use gloves in accordance with manufacturer

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

# D.- Eye and face protection

Pictogram	PPE	Remarks
Mandatory face protection	Panoramic glasses against splash/projections.	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. Use this PPE in accordance with manufacturer's use limitations and OSHA standard 1910.133 (29CFR)

# E.- Bodily protection

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# SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	PPE	Remarks
	Work clothing	Replace before any evidence of deterioration.
	Anti-slip work shoes	Replace before any evidence of deterioration.

# F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

Emergency measure	Standards	Emergency measure	Standards
Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

#### **Environmental exposure controls:**

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

#### 40 CFR Part 59 (VOC):

V.O.C.(weight-percent): 50 % weight
V.O.C. at 68 °F: Non-applicable

# California Air Resources Board (CARB) - VOC Regulatory:

V.O.C. (weight-percent): 50 % weight
V.O.C. at 68 °F: Non-applicable

# South Coast Air Quality Management District (AQMD) - VOC Regulatory:

V.O.C.(weight-percent): 50 % weight V.O.C. at 68 °F: Non-applicable

# **Ozone Transport Commission (OTC) Rules - VOC Regulatory:**

V.O.C.(weight-percent): 50 % weight V.O.C. at 68 °F: Non-applicable

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

# 9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

# Appearance:

Physical state at 68 °F: Liquid

Appearance: Non-applicable \*
Color: Non-applicable \*
Odor: Non-applicable \*
Odour threshold: Non-applicable \*

Volatility:

Boiling point at atmospheric pressure: 277 °F Vapour pressure at 68 °F: 1789 Pa

Vapour pressure at 122 °F: 9436.85 Pa (9.44 kPa)
Evaporation rate at 68 °F: Non-applicable \*

\*Non-applicable due to the nature of the product, not providing information property of its hazards.

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Non-applicable \*

Non-applicable \*

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

**Product description:** 

Density at 68 °F: Non-applicable \* Relative density at 68 °F: Non-applicable \* Non-applicable \* Dynamic viscosity at 68 °F: Non-applicable \* Kinematic viscosity at 68 °F: Kinematic viscosity at 104 °F: Non-applicable \* Concentration: Non-applicable \* pH: Non-applicable \* Non-applicable \* Vapour density at 68 °F: Partition coefficient n-octanol/water 68 °F: Non-applicable \* Solubility in water at 68 °F: Non-applicable \* Solubility properties: Non-applicable \*

Flammability:

Flash Point: 210 °F

Flammability (solid, gas):

Non-applicable \*

Autoignition temperature: 790 °F

Lower flammability limit: Non-applicable \*
Upper flammability limit: Non-applicable \*

**Particle characteristics:** 

Decomposition temperature:

Melting point/freezing point:

Median equivalent diameter:

Non-applicable \*

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties: Non-applicable \*
Oxidising properties: Non-applicable \*
Corrosive to metals: Non-applicable \*
Heat of combustion: Non-applicable \*
Aerosols-total percentage (by mass) of flammable Non-applicable \*

components:

Other safety characteristics:

Surface tension at 68 °F:

Refraction index:

\* Non-applicable \*

\*Non-applicable due to the nature of the product, not providing information property of its hazards.

# SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

# 10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

# 10.3 Possibility of hazardous reactions:

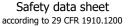
Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

#### 10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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# SECTION 10: STABILITY AND REACTIVITY (continued)

#### 10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

#### 10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO<sub>2</sub>), carbon monoxide and other organic compounds.

# SECTION 11: TOXICOLOGICAL INFORMATION

# 11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

#### **Dangerous health implications:**

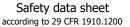
In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

- A- Ingestion (acute effect):
  - Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3
  - Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- B- Inhalation (acute effect):
  - Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
  - Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for inhalation. For more information see section 3.
- C- Contact with the skin and the eyes (acute effect):
  - Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
  - Contact with the eyes: Produces eye damage after contact.
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
  - Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
    - IARC: Non-applicable
  - Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
  - Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- E- Sensitizing effects:
  - Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
  - Skin: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.
- F- Specific target organ toxicity (STOT) single exposure:

Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for inhalation. For more information see section 3.

- G- Specific target organ toxicity (STOT)-repeated exposure:
  - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
  - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.





# SECTION 11: TOXICOLOGICAL INFORMATION (continued)

# Other information:

Non-applicable

#### Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Tulathromycin	LD50 oral	>5000 mg/kg	
CAS: 217500-96-4	LD50 dermal	>5000 mg/kg	
	LC50 inhalation dust	>5 mg/L	
Citric Acid	LD50 oral	5400 mg/kg	Rat
CAS: 77-92-9	LD50 dermal	>5000 mg/kg	
	LC50 inhalation dust	>5 mg/L	

#### **Acute Toxicity Estimate (ATE mix):**

ATE mix		Ingredient(s) of unknown toxicity	
Oral	>5000 mg/kg (Calculation method)	0 %	
Dermal	>5000 mg/kg (Calculation method)	0 %	
LC50 inhalation vapour	>20 mg/L (4 h) (Calculation method)	0 %	

# SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

# 12.1 Ecotoxicity (aquatic and terrestrial, where available):

# Acute toxicity:

Identification	Concentration		Species	Genus
Tulathromycin	LC50	20 mg/L (96 h)	Oncorhynchus mykiss	Fish
CAS: 217500-96-4	EC50	64 mg/L (48 h)	Daphnia magna	Crustacean
	EC50	Non-applicable		
Citric Acid	LC50	1516 mg/L (96 h)	Lepomis macrochirus	Fish
CAS: 77-92-9	EC50	160 mg/L (48 h)	N/A	Crustacean
	EC50	Non-applicable		

# 12.2 Persistence and degradability:

# **Substance-specific information:**

Identification	Degradability		Biodegradability	
Citric Acid	BOD5	Non-applicable	Concentration	10 mg/L
CAS: 77-92-9	COD	Non-applicable	Period	28 days
	BOD5/COD	Non-applicable	% Biodegradable	97 %

# 12.3 Bioaccumulative potential:

# **Substance-specific information:**

Identification	Bioaccumulation potential		
Citric Acid	BCF	3	
CAS: 77-92-9	Pow Log	-1.55	
	Potential	Low	

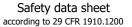
# 12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
Citric Acid	Koc	Non-applicable	Henry	Non-applicable
CAS: 77-92-9	Conclusion	Non-applicable	Dry soil	Non-applicable
	Surface tension	2.045E-2 N/m (663.67 °F)	Moist soil	Non-applicable

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#### 12.5 Results of PBT and vPvB assessment:

Non-applicable





# SECTION 12: ECOLOGICAL INFORMATION (continued)

#### 12.6 Other adverse effects:

Not described

# **SECTION 13: DISPOSAL CONSIDERATIONS**

#### 13.1 Disposal methods:

IT IS THE RESPONSIBILITY OF THE WASTE GENERATOR TO EVALUATE WHETHER HIS WASTES ARE HAZARDOUS BY CHARACTERISTICS OR LISTING.

#### Waste management (disposal and evaluation):

Follow RCRA framework and EPA regulation for to ensure that hazardous waste is managed safely and properly. Waste should not be disposed of to drains. Remind, It is the responsibility of the waste generator to evaluate whether his wastes are hazardous by characteristics or listing. See section 6 for further information about Accidental release measures.

# Regulations related to waste management:

Legislation related to waste management:

40 CFR Solid Wastes - Part 239 through 282.

State regulatory requirements for generators may be more stringent than those in the federal program. Be sure to check the state's policies.

# **SECTION 14: TRANSPORT INFORMATION**

This product is not regulated for transport.

# **SECTION 15: REGULATORY INFORMATION**

#### 15.1 Safety, health and environmental regulations specific for the product in question:

- CALIFORNIA LABOR CODE The Hazardous Substances List: Non-applicable
- California Proposition 65 (the Safe Drinking Water and ToxicEnforcement Act of 1986) Birth defects or other reproductive harm: Non-applicable
- California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986) Cancer: Non-applicable
- CANADA-Domestic Substances List (DSL): Citric Acid (77-92-9)
- CANADA-Non-Domestic Substances List (NDSL): Non-applicable
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Reportable Quantities: Non-applicable
- Hazardous Air Pollutants (Clean Air Act): Non-applicable
- Massachusetts RTK Substance List: Non-applicable
- Minnesota Hazardous substances ERTK: Non-applicable
- New Jersey Worker and Community Right-to-Know Act: Non-applicable
- New York RTK Substancelist: Non-applicable
- NTP (National Toxicology Program): Non-applicable
- OSHA Specifically Regulated Substances (29 CFR 1910.1001-1096); Non-applicable
- Pennsylvania Worker and Community Right-to-Know Law: Non-applicable
- Protective Action Criteria (PAC) with AEGLs, ERPGs, & TEELs: Non-applicable
- Rhode Island Hazardous substances RTK: Non-applicable
- SB-258 Cleaning Product Right to KnowAct : Non-applicable
- The Toxic Substances Control Act (TSCA): Citric Acid (77-92-9)
- Toxic chemical release reporting under EPCRA section 313 (40 CFR Part 372): Non-applicable

# Specific provisions in terms of protecting people or the environment:

It is recommended to use the information provided in this safety data sheet as a foundation for conducting workplace-specific risk assessments. These assessments will help establish the appropriate risk prevention measures for handling, using, storing, and disposing of this product.

# Other legislation:

Take into consideration other applicable federal, state, and local laws and local regulations.

# SECTION 16: OTHER INFORMATION

# Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with Appendix d to 29 CFR 1910.1200 - Safety data sheets

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# Norther Norther

# Safety data sheet according to 29 CFR 1910.1200

# Norbrook Laboratories Ltd - Tulieve Injection for Cattle and Swine - ANDA 200-723 61027

# SECTION 16: OTHER INFORMATION (continued)

# Texts of the legislative phrases mentioned in section 2:

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

#### Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

#### 29 CFR 1910.1200:

Eye Irrit. 2A: H319 - Causes serious eye irritation. Skin Sens. 1: H317 - May cause an allergic skin reaction. STOT SE 3: H335 - May cause respiratory irritation.

# Advice related to training:

According to 29 CFR 1910. 1200, training on chemical hazards is necessary for employees using this product. This training will facilitate their understanding and interpretation of the safety data sheet, as well as the product label.

#### Principal bibliographical sources:

Occupational Safety & Health Administration (OSHA).

#### **Abbreviations and acronyms:**

IMDG: International maritime dangerous goods code IATA: International Air Transport Association ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor LD50: Lethal Dose 50

CL50: Lethal Concentration 50 EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient Koc: Partition coefficient of organic carbon IARC: International Agency for Research on Cancer

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Revised: 4/12/2024

Manufacturer Disclaimer: The information contained in this safety date sheet ("SDS") is based on sources, technical knowledge and current legislation. Furthermore, is based on data believed to be accurate; thus, the company does not assume any liability for its accuracy. The information provided herein cannot be considered a guarantee of the properties of this product and the same is simply a description of the security requirements. The use, occupational methodology and/or conditions for users of this product are not within our awareness or control. It is ultimately the responsibility of the user(s) to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information of this SDS only refers to this product, which should not be used for purposes other than those specified. Finally, the manner in which this product is used and whether there is any infringement of patents is the sole responsibility of the user(s).

END OF SAFETY DATA SHEET

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