



**Norbrook Laboratories Ltd - Tulieve Injection for Cattle and Swine
- ANADA 200-723
Res : 61027**

SECTION 1: IDENTIFICATION

- 1.1 GHS Product identifier:** Norbrook Laboratories Ltd - Tulieve Injection for Cattle and Swine - ANADA 200-723
Res : 61027
- Other means of identification:**
Non-applicable
- 1.2 Recommended use of the chemical and restrictions on use:**
Relevant uses: Veterinary Pharmaceutical Product
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Name, address, and 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
<http://www.norbrook.com>
- 1.4 Emergency phone number:** +44 (0)28 3026 4435

SECTION 2: HAZARD(S) IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
29 CFR 1910.1200:
Classification of this product has been carried out in accordance with paragraph (d) of § 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 dust/fume/gas/mist/vapours/spray.
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:**
Non-applicable
- 3.2 Mixtures:**

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Chemical description: Solution for Injection

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 §1910.1200. Therefore, in accordance with Appendix D to § 1910.1200, the product contains:

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

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 modifications 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 individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

Additional provisions:

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SECTION 5: FIRE-FIGHTING MEASURES (continued)

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 spilled product (See section 8). Evacuate the area and keep out those who do not have protection.

For emergency responders:

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:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current standards 29 CFR 1910 Occupational Safety and Health Standards. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

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 to prevent ergonomic and toxicological risks

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.- Technical measures for storage

Maximum Temp.: 59 - 86 °F

B.- General conditions for storage

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

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:

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

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

There are no occupational exposure limits for the substances contained in the product

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	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's use limitations and OSHA standard 1910.138 (29CFR)

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.- Ocular and facial 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

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

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:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

National volatile organic compound emission standards (40 CFR Part 59):

V.O.C.(weight-percent):	47.16 % weight
V.O.C. at 68 °F:	841.46 kg/m ³ (841.46 g/L)

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:	Not available
Color:	Not available
Odor:	Not available
Odour threshold:	Non-applicable *

Volatility:

Boiling point at atmospheric pressure:	272 °F
Vapour pressure at 68 °F:	1850 Pa
Vapour pressure at 122 °F:	9759.51 Pa (9.76 kPa)
Evaporation rate at 68 °F:	Non-applicable *

Product description:

Density at 68 °F:	1042.4 kg/m ³
Relative density at 68 °F:	1.042
Dynamic viscosity at 68 °F:	Non-applicable *
Kinematic viscosity at 68 °F:	Non-applicable *
Kinematic viscosity at 104 °F:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 68 °F:	Non-applicable *
Partition coefficient n-octanol/water 68 °F:	Non-applicable *
Solubility in water at 68 °F:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Flammability:	
Flash Point:	Non Flammable (>199.4 °F)
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	790 °F
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
Particle characteristics:	
Median equivalent diameter:	Non-applicable

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Non-applicable *
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*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

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

Other safety characteristics:

Surface tension at 68 °F:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant 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.

10.2 Chemical stability:

Chemically stable under the 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

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Not applicable	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 (CO₂), 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 dangerous 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 dangerous 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 dangerous 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 dangerous for inhalation. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous 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 dangerous 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 dangerous 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 dangerous 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 dangerous with sensitising effects. For more information see section 3.
- Cutaneous: 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 dangerous 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 dangerous 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 dangerous 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 dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

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

Acute Toxicity Estimate (ATE mix):

ATE mix		Ingredient(s) of unknown toxicity
Oral	>5000 mg/kg (Calculation method)	Non-applicable
Dermal	63829.79 mg/kg (Calculation method)	0 %
Inhalation	>20 mg/L (4 h) (Calculation method)	Non-applicable



SECTION 12: ECOLOGICAL INFORMATION

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

12.1 Ecotoxicity (aquatic and terrestrial, where available):

Acute toxicity:

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

12.2 Persistence and degradability:

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

12.3 Bioaccumulative potential:

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

12.4 Mobility in soil:

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

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Disposal methods:

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations. In case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See epigraph 6.2.

Regulations related to waste management:

Legislation related to waste management:

40 CFR Part 261- IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

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:

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SECTION 15: REGULATORY INFORMATION (continued)

Toxic chemical release reporting under EPCRA section 313 (40 CFR Part 372): Non-applicable
California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986): Non-applicable
The Toxic Substances Control Act (TSCA) : Citric Acid
Massachusetts RTK - Substance List: Non-applicable
New Jersey Worker and Community Right-to-Know Act: Non-applicable
New York RTK - Substance list: Non-applicable
Pennsylvania Worker and Community Right-to-Know Law: Non-applicable
CANADA-Domestic Substances List (DSL): Citric Acid
CANADA-Non-Domestic Substances List (NDSL): Non-applicable
NTP (National Toxicology Program): Non-applicable
Minnesota - Hazardous substances ERTK: Non-applicable
Rhode Island - Hazardous substances RTK: Non-applicable
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1096): Non-applicable
Hazardous Air Pollutants (Clean Air Act): Non-applicable
Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantities: Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal 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 §1910.1200 - Safety data sheets

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:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

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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Safety data sheet
according to 29 CFR 1910.1200

Norbrook Laboratories Ltd - Tulieve Injection for Cattle and Swine
- ANADA 200-723
Res : 61027

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END OF SAFETY DATA SHEET