



<b>SECTION 1: IDENTIFICATION</b>	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	REXXOLIDE 100 mg/ml solution for injection
<b>Synonyms:</b>	None
<b>Proper Shipping name:</b>	Not applicable
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	Antimicrobial
<b>Uses advised against:</b>	Not for human use.
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name (EU):</b>	Dechra Regulatory B.V.
<b>Address:</b>	Handelsweg 25 5531 AE Bladel The Netherlands
<b>Telephone:</b>	+44 (0) 1756 791311
<b>Fax:</b>	+44 (0) 1756 798604
<b>Website:</b>	www.dechra.com
<b>Email:</b>	Not available
<b>Distributor name (Canada):</b>	Dechra Veterinary Products
<b>Address:</b>	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada
<b>Telephone:</b>	1 855 332-9334
<b>Website:</b>	www.dechra.ca
<b>Email:</b>	Not Available
<b>1.4 Emergency Telephone Numbers</b>	
<b>The Netherlands :</b>	+44 (0) 1756 791311
<b>Canada :</b>	1 855 332-9334

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

**Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).**

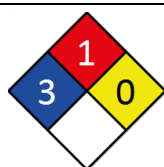
**Considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes (US).**

**Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:**  
 H315 - Skin Corrosion/Irritation Category 2,  
 H318 - Serious Eye Damage Category 1,  
 H317 - Skin Sensitizer Category 1

**Legend:**  
 1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

### 2.2 Label Elements

**GHS Label Elements:**



NFPA 704 diamond

**Signal Word:** **DANGER**

**Hazard pictogram(s):**



**Hazard statement(s):**

H315 – Causes skin irritation  
 H318 – Causes serious eye damage  
 H317 – May cause an allergic skin reaction

**Supplementary Statement(s) EU:**

Not applicable

**Precautionary Statement(s) Prevention:**

P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection  
 P261 - Avoid breathing mist/ vapors/ spray

**Precautionary Statement(s) Response:**

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P302+P352 - IF ON SKIN: Wash with plenty of water and soap.  
 P333+P313 - If skin irritation or rash occurs: Get medical



	advice/attention.
<b>Precautionary Statement(s) Storage:</b>	
	Not applicable.
<b>Precautionary Statement(s) Disposal:</b>	
	P501 – Dispose of contents/ container in accordance with local regulations
<b>2.3 Other Hazard Information</b>	
REACH (EU) Article 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.	

**SECTION 3: INFORMATION ON THE INGREDIENTS**

**3.1 Substances**

See section below for composition of mixtures

**3.2 Mixtures**

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1.217500-96-4 2.Not Available 3.Not Available 4.Not Available	10.0%	Tulathromycin	Skin Sensitizer Category 1, Serious Eye Damage Category 1; H317, H318 [1]
1.57-55-6 2.200-338-0 3.Not Available 4.01-2119457556-29-XXXX 01-2119493630-37-XXXX 01-2119456809-23-XXXX 01-2119987460-31-XXXX	*	Propylene glycol	Eye Irritation Category 2, Skin Corrosion/Irritation Category 2; H319, H315 [1]

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1.7647-01-0 2.231-595-7 3.017-002-00-2 017-002-01-X 4.01-2119484862-27-XXXX 01-2120762784-43-XXXX 01-2120066883-46-XXXX	*	Hydrochloric acid	Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Skin Corrosion/Irritation Category 1B; H335, H314 [2]
1.77-92-9 2.201-069-1 3. Not Available 4.01-2119457026-42-XXXX	*	Citric acid anhydrous	Skin Corrosion/Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Serious Eye Damage Category 1; H315, H335, H318 [1]
1.96-27-5 2.202-495-0 3. Not Available 4.01-2120768144-53-XXXX	*	Monothioglycerol	Acute Toxicity (Oral) Category 4, Acute Toxicity (Dermal) Category 4, Skin Corrosion/Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Skin Sensitizer Category 1, Germ cell mutagenicity Category 2, Eye Irritation Category 2; H302, H312, H315, H335, H317, H341, H319 [1]
1.7732-18-5 2.231-791-2 3. Not Available 4. Not Available	Not specified	Water for Injection	Not applicable
<b>Legend:</b>	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available		

\*Proprietary information



<b>SECTION 4: FIRST AID MEASURES</b>	
<b>4.1 Description of first aid measures</b>	
<b>Eye contact:</b>	Accidental spillage on the eyes should be washed off immediately with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
<b>Skin contact:</b>	Accidental spillage on the skin should be washed off immediately with plenty of soap and water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
<b>Inhalation:</b>	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
<b>Ingestion:</b>	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, do not induce vomiting, seek medical advice and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
<b>Eye contact:</b>	May cause eye irritation.
<b>Skin contact:</b>	May cause skin irritation.
<b>Ingestion:</b>	May cause discomfort if ingested in large quantities
See Section 11 for more detailed information	
<b>4.3 Indication of immediate medical attention and special treatment needed</b>	
Treat symptomatically. Do not induce vomiting. Propylene glycol is a CNS depressant in large doses and may cause hypoglycaemia, lactic acidosis and seizures	



SECTION 5: FIRE FIGHTING MEASURES	
<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Select extinguishing media suitable for surrounding area
<b>Unsuitable:</b>	There is no restriction on the type of extinguisher which may be used
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Fire incompatibility:</b>	Avoid contamination with oxidizing agents.
<b>5.3 Special protective actions for fire-fighters:</b>	
<b>Firefighting:</b>	Use water delivered as a fine spray to control fire and cool adjacent area. <b>Do not</b> approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
<b>Fire / explosion hazard:</b>	Combustible. Slight fire hazard when exposed to heat or flame. On combustion, may emit toxic fumes of carbon monoxide.

SECTION 6: ACCIDENTAL RELEASE MEASURES	
<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	
For information on protective equipment, see section 8	
<b>6.2 Environmental Precautions</b>	
See section 12	
<b>6.3 Methods and material for containment and cleaning up</b>	
Spills are unlikely due to the nature of the product and how it is packaged	
<b>Minor Spills:</b>	Clean up all spills immediately. Avoid breathing vapors and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
<b>Major Spills:</b>	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent, by any means available, spillage from entering drains or water course.



<b>SECTION 7: HANDLING AND STORAGE</b>	
<b>7.1 Precautions for safe handling</b>	
<b>Safe Handling:</b>	Wear suitable protection gloves and clothing when handling the product. When handling, <b>DO NOT</b> eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Keep out of the sight and reach of children.
<b>7.2 Conditions for safe storage, including any incompatibilities</b>	
<b>Suitable Container:</b>	Type I clear glass vial with a fluoropolymer coated chlorobutyl stopper and an aluminum seal. Check that containers are clearly labelled. Available in 50, 100, 250 and 500 ml. Not all sizes may be marketed.
<b>Storage incompatibility:</b>	No known incompatibilities.
<b>7.3 Specific end uses</b>	
Not available	

<b>SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION</b>				
<b>8.1 Control parameters</b>				
<b>DERIVED NO EFFECT LEVEL – DNEL (EU)</b>				
Not Available				
<b>PREDICTED NO EFFECT LEVEL – PNEC (EU)</b>				
Not Available				
<b>OCCUPATIONAL EXPOSURE LIMITS (OEL)</b>				
<b>INGREDIENT DATA</b>				
Not Available				
<b>EMERGENCY LIMITS (EU/US):</b>				
	<b>Material Name</b>	<b>TEEL-1</b>	<b>TEEL-2</b>	<b>TEEL-3</b>
Rexxolide 100 mg/ml Solution for Injection	Not Available	Not Available	Not Available	Not Available
Tulathromycin	Tulathromycin	Not Available	Not Available	Not Available



Propylene glycol	Propylene glycol	30 mg/m <sup>3</sup>	1,300 mg/m <sup>3</sup>	7,900 mg/m <sup>3</sup>
Hydrochloric acid	Hydrochloric acid	Not Available	Not Available	Not Available
Citric acid anhydrous	Citric acid anhydrous	Not Available	Not Available	Not Available
Monothioglycerol	Monothioglycerol	Not Available	Not Available	Not Available
Water	Water	Not Available	Not Available	Not Available
<b>Ingredient</b>	<b>Original IDLH</b>		<b>Revised IDLH</b>	
Tulathromycin	Not Available		Not Available	
Propylene glycol	Not Available		Not Available	
Hydrochloric acid	50 ppm		Not Available	
Citric acid anhydrous	Not Available		Not Available	
Monothioglycerol	Not Available		Not Available	
Water	Not Available		Not Available	

## 8.2 Exposure controls

<b>Appropriate engineering controls:</b>	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
<b>Personal protection:</b>	
<b>Eye and face protection:</b>	Safety glasses with side shields / chemical goggles
<b>Skin protection:</b>	See hand protection below
<b>Hands/ feet protection:</b>	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
<b>Body protection:</b>	Wear appropriate clothing
<b>Other protection:</b>	No special equipment needed when handling small quantities
<b>Thermal hazards:</b>	Not applicable
<b>Respiratory protection:</b>	Not applicable

## 8.3 Environmental exposure controls

See Section 12





## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

**Appearance:** Clear, colorless to slightly yellow solution for injection  
**Container:** Type I clear glass vial with a fluoropolymer coated chlorobutyl stopper and an aluminum seal. Available in 50, 100, 250 and 500 ml. Not all vial sizes may be marketed.  
**Physical state:** Liquid  
**Odor:** Not available  
**Melting point / freezing point (degrees C):** Not applicable  
**Initial boiling point and boiling range:** Not applicable  
**Flash Point:** Not applicable  
**Evaporation rate:** Not applicable  
**Flammability:** Not available  
**Upper/lower flammability or explosive limits:** Not available  
**Vapor pressure:** Not applicable  
**Specific Gravity:** Not available  
**Solubility in water and solvents (mg/l):** Not available  
**Auto ignition temperature (degrees C):** Not available  
**Decomposition temperature (degrees C):** Not available  
**Viscosity: (degrees C):** Not available  
**Explosive properties:** Not available  
**Oxidizing properties:** Not available  
**Partition Coefficient:** Not available  
**Taste:** Not applicable  
**Surface tension:** Not available  
**Volatile component:** Not available  
**Gas group:** Not applicable  
**pH:** Not applicable  
**VOC g/L:** Not applicable

### 9.2 Other information

Not Available

## SECTION 10: STABILITY AND REACTIVITY

<b>10.1 Reactivity:</b>	See Section 7.
<b>10.2 Chemical stability:</b>	Product is considered stable. Hazardous polymerization will not occur.
<b>10.3 Possibility of hazardous reactions:</b>	The product is not considered to be hazardous if used as per instructions. Hazardous polymerization will not occur.
<b>10.4 Conditions to avoid:</b>	No special storage conditions.
<b>10.5 Incompatible materials:</b>	See section 7.
<b>10.6 Hazardous decomposition:</b>	See Section 5.



<b>SECTION 11: TOXICOLOGICAL INFORMATION</b>		
<b>Inhalation:</b>	Inhalation of vapors may cause drowsiness and dizziness.	
<b>Ingestion:</b>	Accidental ingestion of the material may be damaging to the health of the individual. If swallowed, the toxic effects of glycols (dihydric alcohols) are similar to those of alcohol, with depression of the central nervous system, nausea, vomiting, and degenerative changes in the liver and kidney.	
<b>Skin contact:</b>	May cause skin irritation	
<b>Eye contact:</b>	May cause eye irritation	
<b>Chronic:</b>	Long term exposure is not thought to produce chronic effects. May cause sensitization reactions	
<b>Rexxolide 100mg/ml Solution for Injection:</b>	<b>Toxicity</b>	<b>Irritation</b>
	Not available	Not available
Tulathromycin	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
Propylene glycol	<b>Toxicity</b>	<b>Irritation</b>
	Dermal (rabbit) LD50: 11890 mg/kg[2] Inhalation (rat) LC50: >44.9 mg/l/4H[2] Oral (rat) LD50: 20000 mg/kg[2]	Eye (rabbit): 100 mg – mild Eye (rabbit): 500 mg/24h – mild Skin(human):104 mg/3d Intermit Mod Skin(human):500 mg/7days mild
Hydrochloric acid	<b>Acute toxicity</b>	<b>Irritation</b>
	Dermal (rabbit) LD50: >5010 mg/kg[2] Inhalation (rat) LC50: 780.108879 mg/l/1h[2] Oral (rat) LD50: =700 mg/kg[2]	Eye (rabbit): 5mg/30s - mild
Monothioglycerol	<b>Acute toxicity</b>	<b>Irritation</b>
	Dermal (rabbit) LD50: 699 mg/kg[2] Oral (rat) LD50: 673 mg/kg[2]	Not Available



Water	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (rat) LD50: >90000 mg/kg[2]	Not Available
1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances		
<b>Skin corrosion/irritation:</b>		
May cause skin corrosion/ irritation.		
<b>Serious eye damage/irritation:</b>		
May cause irritation		
<b>Respiratory or skin sensitization:</b>		
May cause sensitization		
<b>Germ cell mutagenicity:</b>		
Not available		
<b>Carcinogenicity:</b>		
Not expected to be carcinogenic.		
<b>Reproductive toxicity:</b>		
Not expected to cause reproductive effects		
<b>STOT – single exposure:</b>		
Not available		
<b>STOT–repeated exposure:</b>		
Not available		
<b>Aspiration hazard:</b>		
Not available		

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

	<b>Endpoint</b>	<b>Test duration (hr)</b>	<b>Species</b>	<b>Value</b>	<b>Source</b>
Rextolide 100 mg/ml Solution for Injection	Not available	Not available	Not available	Not available	Not available

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Tulathromycin	Not available	Not available	Not available	Not available	Not available
Propylene glycol	LC50 EC50 EC50 NOEC	96 48 96 168	Fish Crustacea Algae or other aquatic plants Fish	>10 mg/ml 43-500 mg/l 19 mg/l 11-530 mg/ml	2 2 2 2
Hydrochloric acid	LC50 EC50 NOEC	96 96 0.08	Fish Algae or other aquatic plants Fish	70.057 mg/l 344.947 mg/ml 10 mg/l	3 3 4
Citric acid anhydrous	LC50 EC50 EC50 EC0 NOEC	96 48 72 72 16	Fish Crustacea Algae or other aquatic plants Crustacea Crustacea	1-516 mg/l >50 mg/l 990 mg/l <80 mg/ml 153 mg/l	2 2 2 1 4
Monothioglycerol	LC50 EC50 EC50 NOEC	96 48 72 48	Fish Crustacea Algae or other aquatic plants Crustacea	24.408 mg/l 11 mg/ml 4.6 mg/ml 1.8 mg/ml	3 2 2 2
Water	LC50 EC50	96 96	Fish Algae or other aquatic plants	897.520 mg/ml 8768.874 mg/ml	3 3
Legend:	<p><i>Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data</i></p>				

**DO NOT** discard into sewer or waterways.

## 12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Tulathromycin	No data available	No data available
Propylene glycol	LOW	LOW
Hydrochloric acid	LOW	LOW
Citric acid anhydrous	LOW	LOW
Monothioglycerol	LOW	LOW
Water	LOW	LOW



<b>12.3 Bioaccumulative potential</b>	
<b>Ingredient</b>	<b>Bioaccumulative Potential</b>
Tulathromycin	No data available
Propylene glycol	LOW (BCF = 1)
Hydrochloric acid	LOW (LogKOW = 0.5392)
Citric acid anhydrous	LOW (LogKOW = -1.64)
Monothioglycerol	LOW (LogKOW = -0.8383)
Water	LOW (LogKOW = -1.38)
<b>12.4 Mobility in Soil</b>	
<b>Ingredient</b>	<b>Mobility</b>
Tulathromycin	No data available
Propylene glycol	HIGH (KOC = 1)
Hydrochloric acid	LOW (KOC = 14.3)
Citric acid anhydrous	LOW (KOC = 10)
Monothioglycerol	HIGH (KOC = 1)
Water	LOW (KOC = 14.3)
<b>12.5 Results of PBT and vPvB assessment</b>	
Not Applicable	
<b>12.6 Other adverse effects</b>	
Not Available	

<b>SECTION 13: DISPOSAL CONSIDERATIONS</b>	
<b>13.1 Waste treatment methods</b>	
<b>Product / packaging disposal:</b>	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.</p> <p>Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorized landfill. Recycle containers if possible, or dispose of in an authorized landfill.</p>



	<p>Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations (Canada 2015).</p>
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

SECTION 14: TRANSPORT INFORMATION	
<b>Labels required:</b>	
<b>Marine pollutant:</b>	NO
<b>Hazchem:</b>	Not Applicable
<b>Land transport (EU: ADR / US: DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	



## SECTION 15: REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

#### **Tulathromycin (217500-96-4)**

ECHA Classification and labelling inventory  
ECICS

#### **Propylene Glycol (57-55-6)**

Europe EC inventory  
ECHA Classification and labelling inventory  
ECICS  
EINECS  
GESAMP/ EHS Composite list  
IMO IBC Code Chapter 17 & Chapter 18  
IMO MARPOL (Annex II)  
US AIHA / US ATSDR / US DOE / US DOT / US TERA / US SMACs / US TSCA

#### **Hydrochloric acid (7647-01-0)**

ADN – European agreement concerning the International Carriage of Dangerous goods by inland waterways  
Europe EC inventory  
ECHA Classification and labelling inventory / ECICS/ EINECS  
ADR 2011 - European agreement concerning the International Carriage of Dangerous goods by road  
GESAMP/ EHS Composite list  
IMO IBC Code Chapter 17: Summary of minimum requirements  
IMO MARPOL (Annex II)  
IATA Dangerous Goods Regulations  
IMDG Code  
RID 2017  
UN Recommendations on the transport of dangerous goods model regulations  
US AIHA / US ATSDR / US DOE / US DOT / US TERA / US SMACs / US TSCA

#### **Citric acid anhydrous (77-92-9)**

Europe EC inventory  
ECHA Classification and labelling inventory  
ECICS  
EINECS  
GESAMP/ EHS Composite list  
IMO IBC Code Chapter 17  
IMO MARPOL (Annex II)  
US TSCA



**Monothioglycerol (96-27-5)**

ADN – European agreement concerning the International Carriage of Dangerous goods by inland waterways  
 Europe EC inventory  
 ECHA Classification and labelling inventory  
 ECICS  
 ADR 2011 - European agreement concerning the International Carriage of Dangerous goods by road  
 EINECS  
 GESAMP/ EHS Composite list  
 IMO IBC Code Chapter 17: Summary of minimum requirements  
 IMO MARPOL (Annex II)  
 IATA Dangerous Goods Regulations  
 IMDG Code  
 RID 2017  
 UN Recommendations on the transport of dangerous goods model regulations  
 US DOT/ US USPS/ US TSCA

**Water (7732-18-5)**

Europe EC inventory  
 ECHA Classification and labelling inventory  
 ECICS  
 EINECS  
 GESAMP/ EHS Composite list  
 IMO IBC Code Chapter 18  
 US TSCA

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008 and their amendments.

**FEDERAL REGULATIONS:**

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Section 311/312 Hazard Categories**

Immediate (acute) health hazard	YES – may cause skin/ eye irritation and skin sensitization
Delayed (chronic) health hazard	NO
Fire hazard	NO
Pressure hazard	NO
Reactivity hazard	NO

**US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4)**

None reported





<b>STATE REGULATIONS:</b>
<b>US. CALIFORNIA PROPOSITION 65</b> None reported
<b>15.2 Chemical Safety Assessment</b>

<b>ECHA SUMMARY</b>
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Ingredient	CAS number	Index Number	ECHA Dossier
Not applicable			

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
Not applicable			

National Inventory	Status
Australia - AICS	No (tulathromycin)
Canada - DSL	No (tulathromycin)
Canada - NDSL	No (propylene glycol, citric acid anhydrous, hydrochloric acid, water, tulathromycin, sodium hydroxide)
China - IECSC	No (tulathromycin)
Europe - EINEC / ELINCS / NLP	No (tulathromycin)
Japan - ENCS	No (tulathromycin)
Korea - KECI	No (tulathromycin)
New Zealand - NZIoC	No (tulathromycin)
Philippines - PICCS	No (tulathromycin)
USA - TSCA	No (tulathromycin)
<b>Legend:</b>	<i>Yes = All ingredients are on the inventory          No = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>



## SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

### Other Information

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

### Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations

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