



## Safety Data Sheet

Claris Lifesciences Inc.

SDS No. CLI/SDS/TOB.01

### TOBRAMYCIN INJECTION USP

#### 1. PRODUCT IDENTIFICATION

<b>Common/Trade Name:</b>	<b>Tobramycin Injection USP</b>
<b>How Supplied:</b>	<b>Strength:</b>
Fill Volume: 2 mL and 30 mL in Clear Glass Vial USP Type I	40 mg/mL
<b>Chemical Class</b>	Anti infective, Antibacterial
<b>Chemical Name</b>	D-Streptamine, O-3-amino-3-deoxy- $\alpha$ -D-glucopyranosyl-(1 $\rightarrow$ 6)- O- [2, 6- diamino-2, 3, 6 – trideoxy – $\alpha$ - D-ribo-hexopyranosyl- (1 $\rightarrow$ 4)]-2-deoxy-
<b>Formula</b>	C <sub>18</sub> H <sub>37</sub> N <sub>5</sub> O <sub>9</sub>
<b>Product Type</b>	Prescription Drug
<b>Product Use</b>	Pharmaceutical, Injectable
<b>Distributor Name</b>	CLARIS LIFESCIENCES INC
<b>Distributor Address</b>	1445 US HIGHWAY 130, North Brunswick, NJ 08902
<b>Manufacturer's Name</b>	CLARIS INJECTABLES LIMITED
<b>Address</b>	CHACHARWADI-VASANA, AHMEDABAD - 382 213, INDIA.
<b>Telephone Number For Information /Medical Emergency</b>	1-877-7CLARIS (1-877-725-2747)
<b>Date Prepared</b>	September 2016



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## 2. HAZARDOUS IDENTIFICATION

### Emergency Overview

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

### Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

### Signs and Symptoms

None known from work place exposure. In clinical use, adverse effects may include nausea, vomiting, diarrhea, headache, depression, dizziness, impaired balance and eye irritation, skin rashes, respiratory depression, possible kidney injury and hearing loss. Nephrotoxicity manifested by an elevated BUN or serum creatinine level or a decrease in the creatinine clearance has been reported with aminoglycosides. Aminoglycosides have produced vestibular and auditory toxicity in man and in experimental animals. Neurotoxicity manifested by ototoxicity, both vestibular and auditory, can occur in patients treated with tobramycin sulfate. Aminoglycoside-induced ototoxicity is usually irreversible. Allergic reactions during clinical use have also been reported.

### Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to tobramycin sulfate or related products. Pre-existing ocular, renal, auditory or gastrointestinal ailments; pregnancy.

## 3. COMPOSITION INFORMATION

Component	Content mg/ml	CAS
Tobramycin	40.0	[32986-56-4]
Edetate Disodium	0.1	[139-33-3]
Sodium Metabisulfite	3.2	[7681-57-4]
Phenol USP	5.0	[108-95-2]
Sulfuric Acid	q.s. to adjust pH	[7664-93-9]
Sodium Hydroxide	q.s. to adjust pH	[1310-73-2]
Water for Injection	q.s.to 1.0 mL	[7732-18-5]



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#### 4. FIRST-AID MEASURES

##### **Eye contact**

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

##### **Skin contact**

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

##### **Inhalation**

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

##### **Ingestion**

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

#### 5. FIRE-FIGHTING MEASURES:

##### **Flammability**

None anticipated for this aqueous product.

##### **Fire & Explosion Hazard**

None anticipated for this aqueous product.

##### **Extinguishing media**

As with any fire, use extinguishing media appropriate for primary cause of fire.

##### **Special Fire Fighting Procedures**

No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

#### 6. ACCIDENTAL RELEASE MEASURES

##### **Spill Cleanup and Disposal**

Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.



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#### 7. HANDLING AND STORAGE

##### Handling

No special handling required for hazard control under conditions of normal product use.

##### Storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

##### Special Precautions

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION INFORMATION

##### Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. Since protection provided by air purifying respirators is limited, a powered air purifying respirator or supplied air should be considered during an uncontrolled release event, if exposure levels are not known or during events where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

##### Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

##### Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

##### Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

#### 9.0 PHYSICAL AND CHEMICAL DATA

Appearance/Physical State	: Liquid
Color	: Clear and colorless sterile aqueous solution
Odor	: NA
Odor Threshold	: NA
pH	: 3.0 TO 6.5
Melting point/Freezing point	: NA
Initial Boiling Point/Boiling Point Range	: NA
Evaporation Rate	: NA



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#### 9.0 PHYSICAL AND CHEMICAL DATA (Cont...)

Flammability (solid, gas)	: NA
Upper/Lower Flammability or Explosive Limits	: NA
Vapor Pressure	: NA
Vapor Density	: NA
Specific Gravity	: 1.03
Solubility	: Water
Partition coefficient: n-octanol/water	: NA
Auto-ignition temperature	: NA
Decomposition temperature	: NA

#### 10.0 STABILITY AND REACTIVITY

Reactivity	: Not determined.
Chemical Stability	: Stable under standard use and storage conditions.
Hazardous Reactions	: Not determined.
Conditions to avoid	: Not determined.
Incompatibilities	: Not determined.
Hazardous decomposition products	: Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).
Hazardous Polymerization	: Not anticipated to occur with this product.

#### 11. TOXICOLOGICAL INFORMATION

##### Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Tobramycin	100	LD50	Oral	>7500 >11,500	mg/kg mg/kg	Rat Mouse
Tobramycin	100	LD50	Intravenous	104 72.5, 70	mg/kg mg/kg	Rat Mouse
Tobramycin Sulfate	100	LD50	Oral	>10,500	mg/kg	Mouse
Tobramycin Sulfate	100	LD50	Intravenous	126 77	mg/kg mg/kg	Rat Mouse

Aspiration Hazard	: None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	: None anticipated from normal handling of this product.
Ocular Irritation/Corrosion	: None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.



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#### 11. TOXICOLOGICAL INFORMATION (Cont...)

##### **Dermal or Respiratory Sensitization :**

None anticipated from normal handling of this product. Allergic reactions have been reported during the clinical use of this product in patients. In addition, this product contains sodium metabisulfite, a sulfite which may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes, in susceptible people.

##### **Reproductive Effects:**

Aminoglycoside antibiotics cross the placenta, and there have been several reports of total irreversible bilateral congenital deafness in children whose mothers received tobramycin during pregnancy. Also, aminoglycosides may be nephrotoxic to the human fetus.

##### **Mutagenicity:**

The genotoxic potential of tobramycin sulfate has not been evaluated.

##### **Carcinogenicity:**

The carcinogenic potential of tobramycin sulfate has not been evaluated.

##### **Target Organ Effects:**

Aminoglycosides have produced vestibular and auditory toxicity in patients and experimental animals. Based on clinical use, possible target organs include the kidneys, hearing, nervous system, gastrointestinal system, eyes and fetus.

#### 12. ECOLOGICAL INFORMATION

<b>Aquatic Toxicity</b>	: Not determined for product
<b>Persistence/Biodegradability</b>	: Not determined for product
<b>Bioaccumulation</b>	: Not determined for product
<b>Mobility in Soil</b>	: Not determined for product

#### 13. DISPOSAL CONSIDERATIONS

##### **Waste Disposal**

All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

##### **Container Handling and Disposal**

Dispose of container and unused contents in accordance with federal, state and local regulations.



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#### 14. TRANSPORT INFORMATION

ADR/ADG/ DOT STATUS : Not regulated  
IMDG STATUS : Not regulated  
ICAO/IATA STATUS : Not regulated  
Transport Comments : None

#### 15. REGULATORY INFORMATION

##### USA Regulations

<b>RCRA Status</b>	Not Listed
<b>U.S. OSHA Classification</b>	Target Organ Toxin Possible Reproductive Toxin Possible Irritant
<b>GHS Classification</b>	*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:
<b>Hazard Class</b>	Not Applicable
<b>Hazard Category</b>	Not Applicable
<b>Signal Word</b>	Not Applicable
<b>Symbol</b>	Not Applicable
<b>Prevention</b>	P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
<b>Hazard Statement</b>	Not Applicable
<b>Response:</b>	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.

##### EU Classification\*

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Tobramycin Sulfate

<b>Classification(s):</b>	Not Applicable
<b>Symbol:</b>	Not Applicable
<b>Indication of Danger:</b>	Not Applicable
<b>Risk Phrases:</b>	Not Applicable
<b>Safety Phrases:</b>	S23 - Do not breathe vapor. S24 - Avoid contact with skin. S25 - Avoid contact with eyes. S37/39 - Wear suitable gloves and eye/face protection.



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#### 16. OTHER INFORMATION

<b>ACGIH TLV</b>	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
<b>CAS</b>	Chemical Abstracts Service Number
<b>CERCLA</b>	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
<b>DOT</b>	US Department of Transportation Regulations
<b>EEL</b>	Employee Exposure Limit
<b>IATA</b>	International Air Transport Association
<b>LD50</b>	Dosage producing 50% mortality
<b>NA</b>	Not applicable/Not available
<b>NE</b>	Not established
<b>NIOSH</b>	National Institute for Occupational Safety and Health
<b>OSHA PEL</b>	US Occupational Safety and Health Administration – Permissible Exposure Limit
<b>Prop 65</b>	California Proposition 65
<b>RCRA</b>	US EPA, Resource Conservation and Recovery Act
<b>RTECS</b>	Registry of Toxic Effects of Chemical Substances
<b>SARA</b>	Superfund Amendments and Reauthorization Act
<b>STEL</b>	15-minute Short Term Exposure Limit
<b>TSCA</b>	Toxic Substance Control Act
<b>TWA</b>	8-hour Time Weighted Average

The above information is believed to be correct based on our present knowledge but does not purport to be complete. The product is for research use only and for trained personnel. The burden of safe use of this material rests entirely with the user.