

SECTION 1: IDENTIFICATION

Product Identifier

Product Name: Gentamicin Injection USP
Other Name: Gentamicin Sulfate Injection 10 mg/mL and 40 mg/mL
Chemical Family: Mixture

Product Use: Pharmaceutical (Solution for injection, used as antibiotic agent)

Supplier: **Teligent Canada Inc.**
5995 Avebury Road, Suite 804
Mississauga, Ontario L5R 3P9
1-800-656-0793

Manufacturer: **Teligent OÜ**
Akadeemia tee 21/5, Tallinn, Estonia

Emergency Phone Number:
Chemical Emergency Response Unit (Canada): 1-613-946-5690
Poison Control Center (US): 1-800-222-1222

SECTION 2: HAZARD IDENTIFICATION

This pharmaceutical product is for human use under prescribed dosage form. Under normal handling and use, and in a manner consistent with the labeled instructions, this product is not chemically hazardous.

Classification of the Substance or Mixture**GHS Classification**

Skin Sensitization

Category 1

GHS Label Elements, Including Hazard and Precautionary Statements**Pictogram:****Signal Word:**

Warning

Hazard Statements:

H317

May cause an allergic skin reaction.

Precautionary statements:

Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of water.

If skin irritation or rash occurs: Get medical advice/ attention.
 Take off contaminated clothing and wash before reuse.
 Dispose of contents/container in accordance with all local and national regulations.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

Composition of 2 mL Dosage, 10 mg/ml (without Preservative)

Ingredients	CAS Number	Quantity	Acute toxicity, LD50, Oral, Rat
Gentamicin Sulfate Equivalent to Gentamicin	1405-41-0	31.75 mg 20.0 mg	> 5000 mg/kg
Sodium Metabisulfite	7681-57-4	3.2 mg	1540 mg/kg
Sulfuric Acid	7664-93-9	For pH adjustment	2,140 mg/kg
Sodium Hydroxide	1310-73-2	For pH adjustment	No data available
Purified Water	7732-18-5	-	Not applicable

Composition of 2 mL Dosage, 40 mg/ml (with Preservative)

Ingredients	CAS Number	Quantity	Acute toxicity, LD50, Oral, Rat
Gentamicin Sulfate Equivalent to Gentamicin	1405-41-0	127 mg 80 mg	> 5000 mg/kg
Sodium Metabisulfite	7681-57-4	3.2 mg	1540 mg/kg
Sodium Methylparaben	5026-62-0	1.8 mg	> 5000 mg/kg
Sodium Propylparaben	35285-69-9	0.2 mg	> 3700 mg/kg
Sulfuric Acid	7664-93-9	For pH adjustment	2,140 mg/kg
Sodium Hydroxide	1310-73-2	For pH adjustment	No data available
Purified Water	7732-18-5	-	Not applicable

SECTION 4: FIRST AID MEASURES

- After Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
- After Skin Contact:** Remove clothing and wash affected skin with plenty of soap and water. If irritation occurs or persists, get medical attention.
- After Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
- After Ingestion:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Get medical attention.

SECTION 5: FIRE FIGHTING MEASURES

Fire Fighting Instructions: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Hazardous Combustion

Products: No data available.

Fire/Explosion Hazards: Flammable liquid. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at controlled temperature between 15 and 30 °C. Protect from light. For details information refer to the product packaging.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control parameters

Gentamicin Sulfate

No data available

Personal Protection Equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Eye Protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin Protection: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.

Hand Protection: Protective gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Respiratory Protection: Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, wear an appropriate respirator with a protection factor sufficient to control exposures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Colour:	Colourless
Odour:	No data available
Odour threshold:	No data available
Molecular Formula:	Mixture
Molecular Weight:	Mixture
Specific Gravity:	1.0286 g/mL (preservative formulation) 1.002 g/mL (preservative free formulation)
pH:	3.0 – 5.5
Boiling Point:	Mixture
Freezing Point:	Mixture
Solubility in Water:	Miscible in water
Flash Point:	No data available
Vapor Density:	No data available
Vapor Pressure:	No data available
Evaporation Rate:	No data available
Partition Coefficient:	No data available
Flammability:	No data available
Auto-ignition Temperature:	No data available
Decomposition Temperature:	No data available
Viscosity:	No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions: No data available
Conditions to Avoid: Direct sunlight, conditions that might generate heat, and sources of ignition.
Incompatibility: No data available
Hazardous Decomposition Products: Hazardous decomposition products formed under fire conditions: Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides.

SECTION 11: TOXIOLOGICAL INFORMATION

Acute toxicity (Species, Root, Endpoint, Dose)

Gentamicin Sulfate

Rat	Oral	LD50	> 5000 mg/kg
Rat	Intravenous	LD50	52 mg/kg
Rat	Intramuscular	LD50	545 mg/kg

Sodium Metabisulfite

Rat	Oral	LD50	1540 mg/kg
Rat	Dermal	LD50	> 2000 mg/kg

Sulfuric Acid

Rat	Oral	LD50	2140 mg/kg
Rat	Inhalation	LC50 – 2hr	> 510 mg/m ³

Repeated dose toxicity

No toxic effects evident at oral dosage 150 mg/kg/day in rats and 10 mg/kg/day in dogs for one month.

Other information on acute toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Genotoxicity

In vitro genotoxicity studies	Salmonella	Negative
In vitro forward mutation	Escherichia coli	Positive (at cytotoxic dose level)
In vitro ovary cells	Chinese hamster	Negative

Carcinogenicity

Carcinogenicity of the mixture has not been determined. None of the components of this formulation are listed as human carcinogen by IARC, ACGIH or OSHA.

Reproductive toxicity

Fetal auditory and vestibular nerve damage seen in rats study at intramuscular dose 75 mg/kg/day for 12 days

Teratogenicity

No teratogenic effects were evident in guinea-pigs and rabbits

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Gentamicin Sulfate

No data available

Sodium Hydroxide

Toxicity to fish

LC50 - *Gambusia affinis* (Mosquito fish) - 125 mg/l - 96 h

LC50 - *Oncorhynchus mykiss* (rainbow trout) - 45.4 mg/l - 96 h

Sodium Metabisulfite

Toxicity to fish

LC50 – *Oncorhynchus mykiss* (Rainbow Trout) - 150- 220 mg/l – 96 hr

Toxicity to daphnia and other aquatic invertebrates

EC50 – *Daphnia magna* (Water flea) - 89 mg/l – 24 hr

Sulfuric Acid

Toxicity to fish

LC50 – *Gambusia affinis* (Mosquito fish) - 42 mg/l – 96 hr

Toxicity to daphnia and other aquatic invertebrates

EC50 – *Daphnia magna* (Water flea) - 29 mg/l – 24 hr

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with all applicable federal, state and local regulations. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases.

Packaging: Dispose of in accordance with all applicable federal, state and local regulations. Handle packaging in the same way as the product itself.

SECTION 14: TRANSPORTATION INFORMATION

Not regulated for transport under USDOT (transportation by land), IATA (transportation by air) or IMDG (transportation by sea) regulations.

SECTION 15: REGULATORY INFORMATION

The product described in this SDS is regulated under the Federal Food, Drug and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable).

SECTION 16: OTHER INFORMATION

The information contained in this Safety Data Sheet has been compiled from information believed to be accurate. While we believe that the data presented here is factual, Teligent Canada Inc. and its affiliates make no warranty or representation, nor assumes any responsibility in conjunction with the use of this information.

Latest Revision: January 09, 2019