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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**Product Identifier**

MSDS Number: 1087942
Product Name: Isotonic Gentamicin Sulfate Injection

Other means of identification

Product Code(s): 2B0850, 2B0851, 2B0852, 2B0853, 2B0854, 2B0860, 2B0861, 2B0862, 2B0863, 2B0864
Synonyms: None

Recommended use of the chemical and restrictions on use

Product Use: Pharmaceutical.
Product Type: Regulated Prescription Drug
Uses advised against No information available

Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DEERFIELD, ILLINOIS 60015
US: (800) 933-0303
Canada: (855)-584-1368

Emergency telephone number

Rocky Mountain Poison and Drug Center: USA (888) 990-0996
OUTSIDE USA (303) 389-1422
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. HAZARDS IDENTIFICATION**Classification****OSHA Regulatory Status**

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label Elements**Emergency Overview**

The product contains no substances which at their given concentration, are considered to be hazardous to health

Hazards not otherwise classified (HNOC)**Other Information****3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS-No	Weight-%
Gentamicin Sulfate	1405-41-0	<0.3
Sodium Chloride	7647-14-5	<1

Water	7732-18-5	>98
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4. FIRST AID MEASURES

First Aid Measures

General Advice	Treat symptomatically and supportively.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed

No information available.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use foam or all purpose dry chemicals to extinguish.

Specific hazards arising from the chemical

No information available.

Special protective equipment for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental Precautions

See Section 12 for environmental precautions.

Methods and material for containment and cleaning up

Methods for Containment:

If emergency personnel are unavailable, contain spilled material.

Methods for cleaning up

For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Technical measures/precautions: Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions Store at room temperature 25 °C (77 °F). Avoid excessive heat.

Incompatible materials No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Occupational Exposure Limits**

Exposure Limits: This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Gentamicin Sulfate 1405-41-0	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Appropriate engineering controls

Engineering Measures No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Individual protection measures, such as personal protective equipment

Eye protection Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Hand protection Use chemical resistant, impervious gloves.

Skin and body protection Shower at the end of the work day and change Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Respiratory protection No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Physical state: Liquid
Appearance: Aqueous solution
Color: Colorless
Odor: No information available
Odor Threshold: No information available
pH: Approximately 4.0
Melting point / melting range: No information available
Boiling point / boiling range: No information available
Flash point: No information available
Evaporation rate: No information available
Flammability (solid, gas): No information available
Flammable limits in air-upper (%): No information available

Flammable limits in air-lower (%):	No information available
Vapor pressure:	No information available
Vapor Density:	No information available
Density:	No information available
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	No information available
Autoignition temperature:	No information available
Decomposition Temperature:	No information available
Viscosity:	No information available
Explosive Properties:	No information available
Oxidizing Properties:	No information available

Other Information**10. STABILITY AND REACTIVITY****Reactivity**

No data available

Chemical Stability

Stable under recommended storage conditions

Possibility of Hazardous Reactions

None under normal processing

Conditions to Avoid

Heat, flames and sparks.

Incompatible materials

None known

Hazardous Decomposition Products

No data available

11. TOXICOLOGICAL INFORMATION

Component	Inhalation LC50	Dermal LD50	Oral LD50
Gentamicin Sulfate 1405-41-0	-	-	> 5 g/kg (Rat)
Sodium Chloride 7647-14-5	42 g/m ³ 1 h (Rat)	> 10 g/kg (Rabbit)	= 3 g/kg (Rat)
Water 7732-18-5	-	-	> 90 mL/kg (Rat)

Information on likely routes of exposure

Inhalation:	Inhalation not likely under normal use conditions.
Eye contact:	Not expected to cause eye irritation.
Skin contact:	Not expected to cause skin irritation.
Ingestion:	Signs and symptoms of overdosage to aminoglycosides may include nausea, vomiting, diarrhea, headache, depression, dizziness, skin rashes, respiratory depression, possible kidney damage and hearing loss. Renal function effects (may include increased levels of creatinine, BUN, renal failure).

Information on Toxicological Effects

Symptoms: No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation: Not classified.

Corrosivity: Not classified.

Sensitization: Not classified.

Mutagenic effects: Not classified.

Carcinogenic effects: Not classified.

Component	ACGIH	IARC	NTP	OSHA
Gentamicin Sulfate 1405-41-0	-	-	-	-
Sodium Chloride 7647-14-5	-	-	-	-
Water 7732-18-5	-	-	-	-

Reproductive toxicity: Considered fetotoxic based on similar drug data. See patient package insert for additional information.

STOT - single exposure: Not classified.

STOT - repeated exposure: Not classified.

Aspiration Hazard: Not classified.

Numerical measures of toxicity - Product Information**12. ECOLOGICAL INFORMATION**

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Gentamicin Sulfate 1405-41-0	None.	None.	None.	None.

Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h 340.7 - 469.2 mg/L EC50 48 h	4747 - 7824 mg/L LC50 Oncorhynchus mykiss 96 h 12946 mg/L LC50 Lepomis macrochirus 96 h 6020 - 7070 mg/L LC50 Pimephales promelas 96 h 6420 - 6700 mg/L LC50 Pimephales promelas 96 h 5560 - 6080 mg/L LC50 Lepomis macrochirus 96 h 7050 mg/L LC50 Pimephales promelas 96 h	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity

No information available

0.24 % of the mixture consists of components(s) of unknown hazards to the aquatic environment

Persistence and degradability

No information available.

Bioaccumulative potential

No information available

Mobility in soil

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods****Waste from residues/unused products**

In accordance with local and national regulations

Contaminated Packaging

In accordance with local and national regulations.

14. TRANSPORT INFORMATION**DOT**

Not regulated

15. REGULATORY INFORMATION**U.S. Regulations:****TSCA Inventory List -**

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Component	Weight-%	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Gentamicin Sulfate 1405-41-0	<0.3	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride 7647-14-5	<1	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	>98	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Gentamicin Sulfate 1405-41-0	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride 7647-14-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:**Canada DSL Inventory List -**

This product does not comply with DSL

16. OTHER INFORMATION**This data sheet contains changes from the previous version in section(s):**

New GHS format. Changes to Section 1.

Additional information:

Not Available.

Prepared by

Baxter Research & Development

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of Safety Data Sheet