**MSNO**MSN Laboratories Private Limited
R&D Center, Formulation Division.**SAFETY DATA SHEET**

Product Name	Sugammadex Injection 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL)	Page No 1 of 8
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1. Identification**Product Name:** Sugammadex Injection 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL)**Chemical Family:** Mixture**Intended use:** Indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults and pediatric patients undergoing surgery.**Details of the manufacturer:**

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200

2. Hazards Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

3. Composition/Information on Ingredients

C.A.S. No : 343306-79-6

Molecular Formula : $C_{72}H_{104}O_{48}S_8Na_8$

Molecular Weight : 2178.01 g/mol

Chemical Name : $6^A, 6^B, 6^C, 6^D, 6^E, 6^F, 6^G, 6^H$ -Octakis-S-(2-carboxyethyl)-
 $6^A, 6^B, 6^C, 6^D, 6^E, 6^F, 6^G, 6^H$ -octathio- γ -cyclodextrin sodium salt (1:8)**4. First Aid Measures****Eye contact**

- Flush eyes with water as a precaution
- Get medical attention if irritation develops and persists

Skin contact

- Remove immediately contaminated clothes, wash affected skin with water and soap as a precaution
- Get medical attention if symptoms occur

Inhalation

- If inhaled, remove to fresh air
- Get medical attention if symptoms occur

Ingestion

- If swallowed, DO NOT induce vomiting
- Get medical attention if symptoms occur
- Rinse mouth thoroughly with water

Most important symptoms and effects, both acute and delayed

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- None known

Protection of first-aiders

- No special precautions are necessary for first aid responders

Note to physician

- Treat symptomatically and supportively

5. Fire Fighting Measures

Suitable extinguishing media - Water spray jet, alcohol resistant foam, carbon dioxide, Dry chemical

Unsuitable extinguishing media - None known

Specific hazards during fire fighting

- Exposure to combustion products may be a hazard to health

Hazardous combustion products - Carbon oxides

Specific extinguishing methods - Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

- Use water spray to cool unopened containers.

- Remove undamaged containers from fire area if it is safe to do so.

- Evacuate area.

Protection of fire-fighters

- Use personal protective equipment

- Use self-contained breathing apparatus

- Avoid skin contact

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Follow safe handling advice and personal protective equipment recommendations

Environmental protection

- Discharge into the environment must be avoided.

- Prevent further leakage or spillage if safe to do so.

- Prevent spreading over a wide area (e.g., by containment or oil barriers).

- Retain and dispose of contaminated wash water.

- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

- Soak up with inert absorbent material

- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.

- Clean up remaining materials from spill with suitable absorbent.

- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

7. Handling and Storage

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

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Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.

Materials to avoid : Do not store with the following product types: Strong oxidizing agents

Storage Conditions:

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature). Protect from light. When not protected from light, the vial should be used within 5 days.

8. Exposure Controls/Personal Protection

Personal protective equipment

Respiratory protection :

- General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
- Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection :

- Wash hands before breaks and at the end of workday

Eye protection :

- Wear the following personal protective equipment: Safety glasses

Skin and body protection :

- Skin should be washed after contact

Hygiene measures :

- Ensure that eye flushing systems and safety showers are located close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.

9. Physical and Chemical Properties

Description :

200 mg/2 mL (100 mg/mL): A clear, colorless to slightly yellow-brown solution free from visible particles .

500 mg/5 mL (100 mg/mL): A clear, colorless to slightly yellow-brown solution free from visible particles .

10. Stability and Reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical Stability : Stable under normal conditions of use.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to Avoid: None known.

Incompatible Materials: Oxidizing agents.

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Hazardous Decomposition Products: None known

11. Toxicological Information

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Sugammadex:

Acute toxicity (other routes of administration) : LD50 (Rat): > 2,000 mg/kg
Application Route: Intravenous
LD50 (Mouse): > 2,000 mg/kg
Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sugammadex:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Dermal
Species : Mouse
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 429
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Sugammadex:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Test Type: Chromosome aberration test in vitro
Test system: human lymphoblastoid cells
Result: negative

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Genotoxicity in vivo : Test Type: Micronucleus test
: Species: Rat
Result: negative

Germ cell mutagenicity - : Weight of evidence does not support classification as a germ
Assessment : cell mutagen.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Sugammadex:

Effects on fertility : Species: Rat
Application Route: Intravenous injection
Fertility: NOAEL Mating/Fertility: 500 mg/kg body weight
Early Embryonic Development: NOAEL F1: 500 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development
Species: Albino rat
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 500 mg/kg body weight
Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Intravenous injection
Teratogenicity: NOAEL: 200 mg/kg body weight
Developmental Toxicity: NOAEL F1: 200 mg/kg body weight
Embryo-fetal toxicity.: NOAEL F1: 200 mg/kg body weight
Test Type: Development
Species: Rat
Application Route: Intravenous injection
Duration of Single Treatment: 3 Weeks
Developmental Toxicity: LOAEL: 120 mg/kg body weight
Target Organs: Teeth

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

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Repeated dose toxicity

Components:

Sugammadex:

Species : Dog
NOAEL : 250 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks
Number of exposures : daily
Species : Rat
NOAEL : 500 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks
Number of exposures : daily

Aspiration toxicity

Not classified based on available information.

12. Ecological Information

Ecotoxicity

Components:

Sugammadex:

Toxicity to algae : NOEC (Pseudokirchneriella subcapitata (green algae)): 10 mg/l
Method: OECD Test Guideline 201
EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Method: OECD Test Guideline 201
Toxicity to fish : NOEC (Danio rerio (zebra fish)): 100 mg/l
(Chronic toxicity) : Exposure time: 30 d
Method: OECD Test Guideline 210
Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 100 mg/l
aquatic invertebrates (Chronic toxicity) : Exposure time: 21 d
Method: OECD Test Guideline 211
Toxicity to microorganisms : NOEC: 100 mg/l
Exposure time: 30 min
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
EC50: > 100 mg/l
Exposure time: 30 min
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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Persistence and degradability

No data available

Bioaccumulative potential

Components:

Sugammadex:

Partition coefficient: n-octanol/water : log Pow: < -6.4

Mobility in soil

Components:

Sugammadex:

Distribution among environmental compartments : log Koc: 3.4

Other adverse effects

No data available

13. Disposal Considerations

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Empty containers should be taken to an approved waste handling site for
Contaminated packaging : recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. Transport Information

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

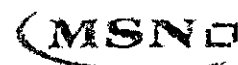
49 CFR

Not regulated as a dangerous good

15. Regulatory Information

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ. CONTROLLED COPY



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SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known
CAS numbers that exceed the threshold (De Minimis)
reporting levels established by SARA Title III, Section 313.

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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