SAFETY DATA SHEET

Sugammadex Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sugammadex Formulation

Manufacturer or supplier's details:
Company name of supplier: MSD
Address: 2000 Galloping Hill Road
          Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use:
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification:
Not a hazardous substance or mixture.

GHS label elements:
Not a hazardous substance or mixture.

Other hazards:
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugammadex</td>
<td>343306-79-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

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

In case of skin contact:
Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

In case of eye contact:
Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed:
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:
None known.

Protection of first-aiders:
No special precautions are necessary for first aid responders.

Notes to physician:
Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
Water spray
### SECTION 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental precautions</td>
<td>Avoid release to the environment. 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.</td>
</tr>
<tr>
<td>Methods and materials for containment and cleaning up</td>
<td>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. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</td>
</tr>
</tbody>
</table>

### SECTION 7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>Use only with adequate ventilation.</td>
</tr>
<tr>
<td>Advice on safe handling</td>
<td>Handle in accordance with good industrial hygiene and safety</td>
</tr>
</tbody>
</table>
practice, based on the results of the workplace exposure assessment.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

Conditions for safe storage: Keep in properly labeled containers.
Store in accordance with the particular national regulations.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugammadex</td>
<td>343306-79-6</td>
<td>TWA</td>
<td>300 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.

Personal protective equipment
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Particulates type
Hand protection

Remarks: 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Aqueous solution
Color: colorless
Odor: odorless
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling: No data available
SAFETY DATA SHEET

Sugammadex Formulation

Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Density: 1 g/cm³
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, dynamic: No data available
  Viscosity, kinematic: No data available
Flow time: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 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

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

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

Carcinogenicity  
Not classified based on available information.

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  
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.
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.

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Sugammadex:**

- **Toxicity to algae/aquatic plants:**
  - **NOEC (Pseudokirchneriella subcapitata (green algae)):** 10 mg/l
  - **Exposure time:** 72 h
  - **Method:** OECD Test Guideline 201

  **EC50 (Pseudokirchneriella subcapitata (green algae)):** > 100 mg/l
  - **Exposure time:** 72 h
  - **Method:** OECD Test Guideline 201

- **Toxicity to fish (Chronic toxicity):**
  - **NOEC (Danio rerio (zebra fish)):** 100 mg/l
  - **Exposure time:** 30 d
  - **Method:** OECD Test Guideline 210

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
  - **NOEC (Daphnia magna (Water flea)):** 100 mg/l
  - **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
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

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 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

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable
SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

The ingredients of this product are reported in the following inventories:

- AICS : not determined
- DSL : not determined
- IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
Sources of key data used to compile the Material Safety Data Sheet:


Revision Date: 06.07.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8