SAFETY DATA SHEET

Sugammadex Formulation

Version 1.12  Revision Date: 09/13/2019  SDS Number: 23759-00013  Date of last issue: 2019/04/24
Date of first issue: 2014/10/21

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sugammadex Formulation

Manufacturer or supplier’s details

Company name of supplier : MSD
Address: Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

Other hazards which do not result in classification
None known.

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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugammadex</td>
<td>343306-79-6</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
</tbody>
</table>

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: None known.
and effects, both acute and delayed
Protection of first-aiders : No special precautions are necessary for first aid responders.
Notes to physician : Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

Unsuitable extinguishing media : None known.

Specific hazards during firefighting : 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.

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Follow safe handling advice and personal protective equipment recommendations.</th>
</tr>
</thead>
</table>

Environmental precautions : 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.
7. HANDLING AND STORAGE

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: Use only with adequate ventilation.
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.
Avoidance of contact: Oxidizing agents
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.

Storage
Conditions for safe storage: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents
Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>200 µg/m³</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.

9. PHYSICAL AND CHEMICAL PROPERTIES
### Appearance
- Aqueous solution

### Colour
- Colourless

### Odour
- Odourless

### Odour Threshold
- No data available

### pH
- No data available

### Melting point/freezing point
- No data available

### Initial boiling point and boiling range
- No data available

### 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

### Vapour pressure
- No data available

### Relative vapour density
- No data available

### Density
- 1 g/cm³

### Solubility(ies)
- Water solubility: No data available

### Partition coefficient: n-octanol/water
- No data available

### Auto-ignition 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.
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Molecular weight: No data available
Particle size: No data available

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.

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 sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Sugammadex:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Dermal
Species: Mouse
Assessment: Does not cause skin sensitisation.
Method: OECD Test Guideline 429
**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 foetal development**
- Test Type: Embryo-foetal development
  - Species: Albino rat
  - Application Route: Intravenous injection
  - Developmental Toxicity: NOAEL: 500 mg/kg body weight

  - Test Type: Embryo-foetal development
    - Species: Rabbit
    - Application Route: Intravenous injection
    - Teratogenicity: NOAEL: 200 mg/kg body weight
    - Developmental Toxicity: NOAEL F1: 200 mg/kg body weight
    - Embryo-foetal 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.

### 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

**Hazardous to the ozone layer**
Not applicable

**Other adverse effects**
No data available

### 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.

### 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.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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

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