SAFETY DATA SHEET

Sugammadex Formulation

Section 1: Identification

Product name : Sugammadex Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

Section 2: Hazard identification

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
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; 30</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.
**SAFETY DATA SHEET**

**Sugammadex Formulation**

<table>
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<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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</thead>
</table>

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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Unsuitable extinguishing media</th>
<th>Specific hazards during firefighting</th>
<th>Hazardous combustion products</th>
<th>Specific extinguishing methods</th>
<th>Special protective equipment for firefighters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water spray</td>
<td>None known.</td>
<td>Exposure to combustion products may be a hazard to health.</td>
<td>Carbon oxides</td>
<td>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.</td>
<td>Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.</td>
</tr>
<tr>
<td>Alcohol-resistant foam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbon dioxide (CO2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry chemical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Section 6: Accidental release measures

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Environmental precautions</th>
<th>Methods and materials for containment and cleaning up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow safe handling advice and personal protective equipment recommendations.</td>
<td>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.</td>
<td>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</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Sugammadex Formulation

Version 1.11  Revision Date: 09/13/2019  SDS Number: 23766-00012  Date of last issue: 15.10.2018  Date of first issue: 21.10.2014

certain local or national requirements.

Section 7: Handling and storage

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.
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 labelled 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

Components 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>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.

Section 9: Physical and chemical properties

Appearance: Aqueous solution
Colour: colourless
### Odour
- **Odour**: Odourless

### Odour Threshold
- **Odour Threshold**: No data available

### pH
- **pH**: No data available

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

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

### Flash point
- **Flash point**: No data available

### Evaporation rate
- **Evaporation rate**: No data available

### Flammability (solid, gas)
- **Flammability (solid, gas)**: Not applicable

### Flammability (liquids)
- **Flammability (liquids)**: No data available

### Upper explosion limit / Upper flammability limit
- **Upper explosion limit / Upper flammability limit**: No data available

### Lower explosion limit / Lower flammability limit
- **Lower explosion limit / Lower flammability limit**: No data available

### Vapour pressure
- **Vapour pressure**: No data available

### Relative vapour density
- **Relative vapour density**: No data available

### Density
- **Density**: 1 g/cm³

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

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

### Auto-ignition temperature
- **Auto-ignition temperature**: No data available

### Decomposition temperature
- **Decomposition temperature**: No data available

### Viscosity
- **Viscosity, dynamic**: No data available
- **Viscosity, kinematic**: No data available

### Flow time
- **Flow time**: No data available

### Explosive properties
- **Explosive properties**: Not explosive

### Oxidizing properties
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.

### Molecular weight
- **Molecular weight**: No data available

### Particle size
- **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

Exposure routes: 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
Result: negative
Chronic toxicity

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:
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.

### 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.

National Regulations
** SAFETY DATA SHEET **

** Sugammadex Formulation **

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<th>Version</th>
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</table>

** NZS 5433 **
Not regulated as a dangerous good

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**Section 15: Regulatory information**

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

**HSNO Approval Number**
Not applicable

**HSW Controls**
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

**The components of this product are reported in the following inventories:**

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

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**Section 16: Other information**

**Further information**
Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

**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
SAFETY DATA SHEET

Sugammadex Formulation

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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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

NZ / EN