**SAFETY DATA SHEET**

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

**Sugammadex Formulation**

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</tbody>
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**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

1.1 **Product identifier**

Trade name : Sugammadex Formulation

1.2 **Relevant identified uses of the substance or mixture and uses advised against**

Use of the Substance/Mixture : Pharmaceutical

1.3 **Details of the supplier of the safety data sheet**

Company : MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 **Emergency telephone number**

1-908-423-6000

**SECTION 2: Hazards identification**

2.1 **Classification of the substance or mixture**

Classification T.R. SEA No 28848
Not a hazardous substance or mixture.

2.2 **Label elements**

Labelling T.R. SEA No 28848
Not a hazardous substance or mixture.

2.3 **Other hazards**

None known.

**SECTION 3: Composition/information on ingredients**

3.2 **Mixtures**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>

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SECTION 4: First aid measures

4.1 Description of first aid measures

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

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.

4.2 Most important symptoms and effects, both acute and delayed
None known.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
5.3 Advice for firefighters

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

- **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.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- **Personal precautions**: Follow safe handling advice and personal protective equipment recommendations.

### 6.2 Environmental precautions

- **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.

### 6.3 Methods and material for containment and cleaning up

- **Methods for 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling
Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSOMAL 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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage : Do not store with the following product types: Strong oxidizing agents.

7.3 Specific end use(s)
Specific use(s) : No data available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>

8.2 Exposure controls

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

Personal protective equipment
Eye protection : Wear the following personal protective equipment: Safety glasses
Equipment should conform to TS EN 166

Hand protection

Remarks
Skin and body protection : Skin should be washed after contact.
Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
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Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
- **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
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Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

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

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Assessment</td>
<td>Does not cause skin sensitisation.</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 429</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Sugammadex:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test system</td>
<td>Test Type: Chromosome aberration test in vitro</td>
</tr>
<tr>
<td>Genotoxicity in vitro</td>
<td>Method: OECD Test Guideline 471</td>
</tr>
<tr>
<td>Result</td>
<td>Test system: human lymphoblastoid cells</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Genotoxicity in vivo:
| Species                 | Test Type: Micronucleus test                     |
| Result                  | Species: Rat                                     |
| Test system             | 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.
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**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
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12.1 Toxicity

**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 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

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

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - NOEC: 100 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211

**Aspiration toxicity**
Not classified based on available information.

**SECTION 12: Ecological information**

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

**Components:**

**Sugammadex:**
- Partition coefficient: n-octanol/water: log Pow: < -6.4
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12.4 Mobility in soil

**Components:**

Sugammadex:
Distribution among environmental compartments: log Koc: 3.4

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.
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SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances,mixtures and articles (Annex 17)

Other regulations:

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

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

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Mari-
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Further information


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.

TR / EN