SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sugammadex Formulation

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 (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

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

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Date of first issue: 21.10.2014

<table>
<thead>
<tr>
<th>Substances with a workplace exposure limit:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugammadex</td>
</tr>
<tr>
<td>343306-79-6</td>
</tr>
<tr>
<td>&gt;=10 - &lt; 20</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

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/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.

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

Occupational Exposure Limits

<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 BS EN 166

Hand protection

Remarks:
Wash hands before breaks and at the end of workday.

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.

Filter type:
Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
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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
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
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:
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

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: Embryotoxicity
  - Species: Albino rat
  - Application Route: Intravenous injection
  - Developmental Toxicity: NOAEL: 500 mg/kg body weight

- Test Type: Embryotoxicity
  - 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.

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**

12.1 Toxicity

**Components:**

**Sugammadex:**
- Toxicity to algae/aquatic: NOEC (Pseudokirchneriella subcapitata (green algae)): 10
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plants

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l

Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Test Type: Respiration inhibition</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 min</td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

EC50: > 100 mg/l

Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Species: Danio rerio (zebra fish)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 d</td>
<td>Method: OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

NOEC: 100 mg/l

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Species: Daphnia magna (Water flea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 d</td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

NOEC: 100 mg/l

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Sugammadex:

Partition coefficient: n-octanol/water

log Pow: < -6.4

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.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
- REACH - List of substances subject to authorisation (Annex XIV): Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
- Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
- REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### 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.

### 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 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSi - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Sub-
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stances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioac-
cumulative

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.

GB / EN