

# 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

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
1.5	23.03.2020	2805475-00006	Date of first issue: 18.05.2018

### 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 Sub-stance/Mixture : Pharmaceutical

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

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

National Poison Control Center (UZEM): 114  
Emergency: 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

##### Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)

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	Registration number		
Substances with a workplace exposure limit :			
Sugammadex	343306-79-6		$\geq 10 - < 20$

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 (CO<sub>2</sub>)  
Dry chemical

- Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides

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### 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

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Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.  
Advice on safe handling : Use only with adequate ventilation.  
: 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sugammadex	343306-79-6	TWA	200 µg/m3	Internal

### 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 : 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.  
Equipment should conform to TS EN 143

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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

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

Not classified based on available information.

## SECTION 12: Ecological information

### 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

### 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 K<sub>oc</sub>: 3,4

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

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## 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.

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## 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, : Not applicable  
placing on the market and use of certain dangerous  
substances, mixtures and articles (Annex 17)  
Regulation on Persistent Organic Pollutants (Number : Not applicable  
30595)  
Regulation on prevention of major industrial accidents. Reg number 30702  
Not applicable

##### Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".  
Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.  
Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

##### 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 - In-

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ternational 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; 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

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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.

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