

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Sugammadex Formulation

Version 1.19      Revision Date: 09/26/2023      SDS Number: 23742-00020      Date of last issue: 03/20/2023  
Date of first issue: 10/21/2014

### SECTION 1. IDENTIFICATION

Product name : Sugammadex Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Not a hazardous substance or mixture.

#### GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### Other hazards

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Sugammadex	No data available	343306-79-6	$\geq 10 - < 30$ *

\* Actual concentration or concentration range is withheld as a trade secret

### 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.  
Rinse mouth thoroughly with water.

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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

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : 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 fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
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 diking or other appropriate containment to keep material from spreading. If diked 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.

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Sections 13 and 15 of this SDS provide information regarding 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.
- Conditions for safe storage : Keep in properly labeled containers.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sugammadex	343306-79-6	TWA	300 µg/m <sup>3</sup> (OEB 2)	Internal

- 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.
- 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : Aqueous solution

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Color	:	colorless
Odor	:	odorless
Odor 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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	1 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition 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

### 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

#### 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 sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

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### Components:

#### **Sugammadex:**

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Dermal
Species	:	Mouse
Assessment	:	Does not cause skin sensitization.
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 fetal development	:	Test Type: Embryo-fetal development Species: Albino rat Application Route: Intravenous injection Developmental Toxicity: NOAEL: 500 mg/kg body weight
		Test Type: Embryo-fetal development Species: Rabbit

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Application Route: Intravenous injection  
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

### 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

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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 : Do not dispose of waste into sewer.  
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



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### 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.

### Domestic regulation

### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

### The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; 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

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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; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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

Revision Date : 09/26/2023  
Date format : mm/dd/yyyy

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