

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sugammadex Formulation

Version 6.1      Revision Date: 10/23/2025      SDS Number: 23770-00025      Date of last issue: 04/14/2025  
Date of first issue: 10/21/2014

### SECTION 1. IDENTIFICATION

Product name : Sugammadex Formulation

#### 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 OSHA Hazard Communication Standard (29 CFR 1910.1200)**

#### Hazards for the product as supplied

Not a hazardous substance or mixture.

#### Other hazards

None known.

#### GHS label elements

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Sugammadex	343306-79-6*	$\geq 7 - \leq 13$	TSC

\* Indicates that the identifier is a CAS No.

TSC- the 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
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

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## Sugammadex Formulation

Version 6.1      Revision Date: 10/23/2025      SDS Number: 23770-00025      Date of last issue: 04/14/2025  
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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.

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	500 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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

Hand protection	circumstance where air purifying respirators may not provide adequate 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
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

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.
Molecular weight	:	No data available
Particle characteristics	:	
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
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LD50 (Mouse): > 2,000 mg/kg

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

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.

### 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
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	:	Test Type: Chromosome aberration test in vitro Test system: human lymphoblastoid cells Result: negative
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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.

IARC	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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OSHA	No component of this product present at levels greater than or equal to 0.1% is
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# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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  
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

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



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## Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

### Mobility in soil

#### Components:

#### **Sugammadex:**

Distribution among environmental compartments : log K<sub>oc</sub>: 3.4

#### **Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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 IMO instruments**

Not applicable for product as supplied.

### **Domestic regulation**

#### **49 CFR**

Not regulated as a dangerous good

### **Special precautions for user**

Not applicable

## SECTION 15. REGULATORY INFORMATION

### **CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

### **SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

### **SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : No SARA Hazards

# SAFETY DATA SHEET

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## Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

Water	7732-18-5
Sugammadex	343306-79-6

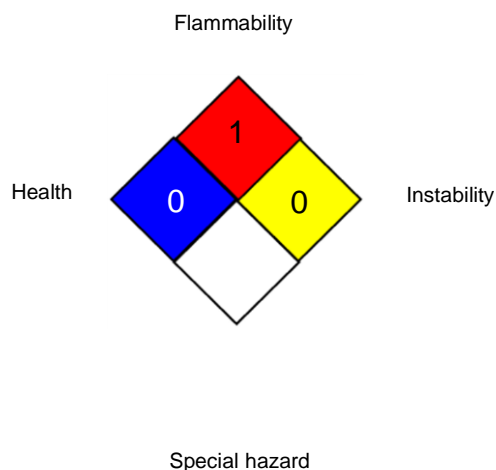
**The ingredients of this product are reported in the following inventories:**

AICS	: not determined
CA. DSL	: not determined
IECSC	: not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	/	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule;

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6.1	10/23/2025	23770-00025	Date of first issue: 10/21/2014

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; HMIS - Hazardous Materials Identification System; 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 Organization 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

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 : 10/23/2025

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.

US / Z8