

Sugammadex Formulation

Version Revision Date: MSDS Number: Date of last issue: 10/21/2014
1.3 03/26/2015 23770-00002 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 : One Merck Drive
Whitehouse Station - New Jersey - USA 08889

Telephone : 908-423-1000

Telefax : 908-735-1496

Emergency telephone : 908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical Name	CAS-No.	Concentration (%)
Sugammadex	343306-79-6	>= 10 - < 20

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.

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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 Dry chemical Carbon dioxide (CO ₂)
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 and personal protective equipment recommendations.
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.

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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.
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.
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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sugammadex	343306-79-6	TWA	800 µg/m ³	Merck

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

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supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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 : Ensure that eye flushing systems and safety showers are located 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) : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Density : 1 g/cm³

Solubility(ies)

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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
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

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.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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Respiratory or skin sensitization

Skin sensitization: Not classified based on available information.

Respiratory sensitization: Not classified based on available information.

Ingredients:

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.

Ingredients:

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
Species: human lymphoblastoid cells
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Method: OECD Test Guideline 474
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.

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.

OSHA

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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.

Ingredients:

Sugammadex:

Effects on fertility : Species: Rat

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Application Route: Intravenous injection
Fertility: No observed adverse effect level (Mating/Fertility):
500 mg/kg body weight
Early Embryonic Development: No observed adverse effect
level F1: 500 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development
Species: Albino rat
Application Route: Intravenous injection
Teratogenicity: NOAEL (No observed adverse effect level):
500 mg/kg body weight
Developmental Toxicity: No observed adverse effect level F1:
500 mg/kg body weight
Embryo-fetal toxicity.: No observed adverse effect level F1:
500 mg/kg body weight

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Intravenous injection
Teratogenicity: NOAEL (No observed adverse effect level):
200 mg/kg body weight
Developmental Toxicity: No observed adverse effect level F1:
200 mg/kg body weight
Embryo-fetal toxicity.: No observed adverse effect level F1:
200 mg/kg body weight

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity**Ingredients:****Sugammadex:**

Species: Dog
NOAEL: 250 mg/kg
Application Route: Intravenous
Exposure time: 4 Weeks
Number of exposures: daily

Species: Rat
NOAEL: 30 mg/kg
Application Route: Intravenous
Exposure time: 4 Weeks
Number of exposures: daily

Aspiration toxicity

Not classified based on available information.

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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Ingredients:****Sugammadex:**

Toxicity to algae	: 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 bacteria	: 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**Ingredients:****Sugammadex:**

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

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	: Dispose of in accordance with local regulations.
Contaminated packaging	: Dispose of as unused product. Empty containers should be taken to an approved waste han-

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ding site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**International Regulation****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**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium hydroxide	1310-73-2	1000	*
Hydrochloric acid	7647-01-0	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 311/312 Hazards : No SARA Hazards

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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	70 - 90 %
Sugammadex	343306-79-6	10 - 20 %

New Jersey Right To Know

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Sugammadex	343306-79-6	10 - 20 %

California Prop 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

AICS : not determined

DSL : not determined

IECSC : not determined

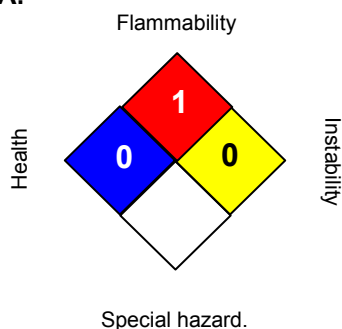
Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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 : 03/26/2015

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

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 guid-

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ance 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