

Sugammadex Formulation

Version Revision Date: SDS Number: Date of last issue: 09/13/2019
4.3 03/23/2020 23770-00014 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 : 2000 Galloping Hill Road
 Kenilworth - New Jersey - U.S.A. 07033
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

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|-------------|-----------------------|
| Sugammadex | 343306-79-6 | >= 10 - < 20 |

Actual concentration 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.
Most important symptoms : None known.
and effects, both acute and
delayed
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

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- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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 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.
- 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.
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SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.

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- 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

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 | 200 µg/m ³ | 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 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 : 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

SAFETY DATA SHEET



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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/cm³

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.

Molecular weight : No data available

Particle size : No data available

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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.

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

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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.

- | | |
|-------------|--|
| 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 component of this product present at levels greater than or equal to 0.1% is 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 Teratogenicity: NOAEL: 200 mg/kg body weight Developmental Toxicity: NOAEL F1: 200 mg/kg body weight |

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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

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 100 mg/l
 Exposure time: 30 d

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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 : 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****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

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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

| Components | 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 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

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

DSL : not determined

IECSC : not determined

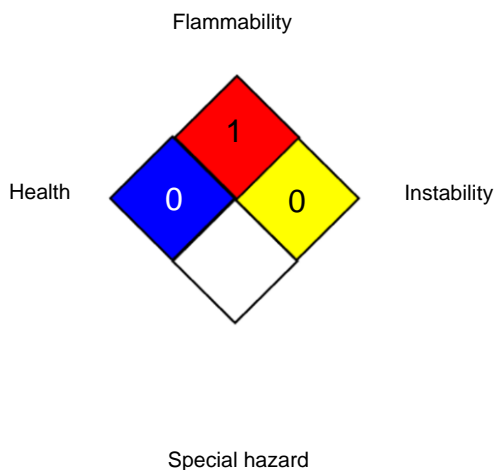
SECTION 16. OTHER INFORMATION

Further information

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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

AICS - Australian Inventory of Chemical Substances; 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 Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); EC_x - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - 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 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; 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, Authorisation 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; 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

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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 : 03/23/2020

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