

# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 1.18 28.09.2024 23733-00019 Date of first issue: 21.10.2014

#### **SECTION 1. IDENTIFICATION**

Product name : Sugammadex Formulation

Manufacturer or supplier's details

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor

Buenos Aires, Argentina C1001AFB

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

#### **GHS Classification**

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 which do not result in classification

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

#### **SECTION 4. FIRST AID MEASURES**

In case of eye contact

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.

Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.



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> Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and None known.

delayed

Protection of first-aiders Notes to physician

No special precautions are necessary for first aid responders.

Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES** 

Water spray Suitable extinguishing media

> 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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec: : tive equipment and emer-

gency procedures

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Avoid release to the environment. Environmental precautions

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

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



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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.

Do not store with the following product types: Materials to avoid

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/m3 (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

Wash hands before breaks and at the end of workday. Remarks Eye protection

Wear the following personal protective equipment:

Safety glasses

Skin should be washed after contact. Skin and body protection

Hygiene measures If exposure to chemical is likely during typical use, provide

eve flushing systems and safety showers close to the

working place.



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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

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



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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 reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Sugammadex:

Acute toxicity (other routes of : LD50 (Rat): > 2.000 mg/kg

administration) 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

Application Route: Intravenous injection

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 tox-

icity)

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/lExposure 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 environ-

mental 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

**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.

Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents

Registry.

: Not applicable

Control of precursors and essential chemicals for the

preparation of drugs.

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

**Further information** 

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

#### 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



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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 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

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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