

# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/03/20 4.0 2023/09/26 23759-00021 Date of first issue: 2014/10/21

# 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Sugammadex Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

# GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

#### **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.

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

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

# 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.



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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.

No special precautions are necessary for first aid responders.

If swallowed If swallowed, DO NOT induce vomiting.

None known.

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

Most important symptoms and effects, both acute and

Protection of first-aiders

delayed

Notes to physician Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

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 firefighters

Wear self-contained breathing apparatus for firefighting if nec-

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Follow safe handling advice (see section 7) and personal pro-

tective 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

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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.



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Clean up remaining materials from spill with suitable absor-

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.

#### 7. HANDLING AND STORAGE

Handling

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 as-

sessment

Take care to prevent spills, waste and minimize release to the

environment.

Avoidance of contact : Oxidizing agents

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.

**Storage** 

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / 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.



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Personal protective equipment

Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state Aqueous solution

Colour colourless

Odour odourless

Odour Threshold No data available

No data available Melting point/freezing point

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit / Lower flammability limit No data available

Flash point No data available

No data available Decomposition temperature

No data available pΗ

Evaporation rate No data available

Auto-ignition temperature No data available

Viscosity

No data available Viscosity, dynamic

Viscosity, kinematic No data available



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Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Density and / or relative density

Density : 1 g/cm<sup>3</sup>

Relative vapour density : 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

## 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

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

Hazardous decomposition

products

No hazardous decomposition products are known.

#### 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:



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administration)

Acute toxicity (other routes of : 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 sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

# Sugammadex:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Dermal Species : Mouse

: Does not cause skin sensitisation. Assessment

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.



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## 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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Albino rat

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 500 mg/kg body weight

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Intravenous injection

Developmental Toxicity: NOAEL F1: 200 mg/kg body weight Embryo-foetal 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



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Exposure time 4 Weeks Number of exposures daily

**Aspiration toxicity** 

Not classified based on available information.

#### 12. ECOLOGICAL INFORMATION

# **Ecotoxicity**

#### **Components:**

# Sugammadex:

Toxicity to algae/aquatic NOEC (Pseudokirchneriella subcapitata (green algae)): 10 plants 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

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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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log Koc: 3.4

#### Mobility in soil

# **Components:**

# Sugammadex:

Distribution among environ-

mental compartments

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

## International Regulations

**UNRTDG** 

**UN** number : Not applicable Proper shipping name : Not applicable : Not applicable Class Subsidiary risk : Not applicable Packing group : Not applicable Labels Not applicable

IATA-DGR

Not applicable UN/ID No. Proper shipping name Not applicable Not applicable Class Not applicable Subsidiary risk Not applicable Packing group Not applicable Labels Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen: :

ger aircraft)

Not applicable

**IMDG-Code** 

**UN** number Not applicable Proper shipping name Not applicable Not applicable Class Subsidiary risk Not applicable Packing group Not applicable



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Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

## Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

Refer to section 15 for specific national regulation.

#### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

#### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

## **Harmful Substances Required Permission for Manufacture**

Not applicable

# **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

# **Substances Subject to be Notified Names**

Not applicable

# **Substances Subject to be Indicated Names**

Not applicable

## Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

# **Ordinance on Prevention of Lead Poisoning**

Not applicable



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## Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

#### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

# Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

## **Poisonous and Deleterious Substances Control Law**

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

## Not applicable

# **High Pressure Gas Safety Act**

Not applicable

## **Explosive Control Law**

Not applicable

#### **Vessel Safety Law**

Not regulated as a dangerous good

## **Aviation Law**

Not regulated as a dangerous good

## Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

#### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

# Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined



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#### 16. OTHER INFORMATION

### **Further information**

Sources of key data used to : compile the Safety Data Sheet

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

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

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

Date format : yyyy/mm/dd

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 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.



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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.

JP / EN