

# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Sugammadex Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Pharmaceutical

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

117 16th Road

1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

+1-908-423-6000

### **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

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

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.



# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)		
	Registration number				
Substances with a workplace exposure limit :					
Sugammadex	343306-79-6		>= 10 - < 20		

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

### 4.1 Description of first aid measures

Protection of first-aiders : No special precautions are necessary for first aid responders.

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, DO NOT induce vomiting.

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

#### 4.2 Most important symptoms and effects, both acute and delayed

None known.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

#### **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.



# **Sugammadex Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 26.09.2023 28.09.2024 23771-00022 Date of first issue: 21.10.2014 3.6

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

: Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

ucts

#### 5.3 Advice for firefighters

Special protective equipment:

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary. Use personal protective equipment.

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

Evacuate area.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

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

tective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for 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. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.



# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

#### **SECTION 7: Handling and storage**

7.1 Precautions for safe 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.

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 contami-

nated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store in accordance with

the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Gases

7.3 Specific end use(s)

Specific use(s) : No data available

### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sugammadex	343306-79- 6	TWA	300 μg/m3 (OEB 2)	Internal

#### 8.2 Exposure controls

### **Engineering measures**

Ensure adequate ventilation, especially in confined areas.

Minimize workplace exposure concentrations.

Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:

Safety glasses

Hand protection

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

Skin and body protection : Skin should be washed after contact.

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



# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type (P)

#### **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Appearance : Aqueous solution

Colour : colourless Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

Flash point

and boiling : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

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

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : No data available

octanol/water

Auto-ignition 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.



# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### **SECTION 11: Toxicological information**

### 11.1 Information on toxicological effects

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 :

administration)

LD50 (Rat): > 2.000 mg/kg Application Route: Intravenous

LD50 (Mouse): > 2.000 mg/kg Application Route: Intravenous



# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

#### 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

Assessment : Does not cause skin sensitisation.

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- As-

sessment

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



# **Sugammadex Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 3.6
 28.09.2024
 23771-00022
 Date of first issue: 21.10.2014

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
Exposure time : 4 Weeks
Number of exposures : daily

#### **Aspiration toxicity**

Not classified based on available information.



# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### **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 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

Toxicity to fish (Chronic tox-

icity)

NOEC: 100 mg/l Exposure time: 30 d

Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 100 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Method: OECD Test Guideline 211

#### 12.2 Persistence and degradability

No data available

#### 12.3 Bioaccumulative potential

#### **Components:**

Sugammadex:

Partition coefficient: n-

log Pow: < -6,4

octanol/water

#### 12.4 Mobility in soil

### **Components:**

Sugammadex:

Distribution among environmental compartments : log Koc: 3,4



# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

#### 12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### 12.6 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

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.

### **SECTION 14: Transport information**

### 14.1 UN number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
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### 14.3 Transport hazard class(es)



## **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

#### 14.6 Special precautions for user

Not applicable

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

### **SECTION 15: Regulatory information**

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

#### Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by



# **Sugammadex Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 3.6 28.09.2024 23771-00022 Date of first issue: 21.10.2014

Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

### **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 Agency, http://echa.europa.eu/

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

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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