

Sugammadex Formulation

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 2.2 28.09.2024 23766-00020 Date of first issue: 21.10.2014

Section 1: Identification

Product name : Sugammadex Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800

CHEMCALL)

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: Hazard 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

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.



Sugammadex Formulation

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 28.09.2024 23766-00020 Date of first issue: 21.10.2014

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

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 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 firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

Use personal protective equipment.

Section 6: Accidental release measures

Personal precautions, protective 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

parriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages



Sugammadex Formulation

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 2.2 28.09.2024 23766-00020 Date of first issue: 21.10.2014

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. 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.

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 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 contaminated clothing before re-use.

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

Section 8: Exposure controls/personal protection

Components 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



Sugammadex Formulation

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

 2.2
 28.09.2024
 23766-00020
 Date of first issue: 21.10.2014

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.

Section 9: 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

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

Vapour pressure : No data available

Relative vapour density : No data available

Density : 1 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available



Sugammadex Formulation

Version SDS Number: Date of last issue: 26.09.2023 **Revision Date:** 2.2 28.09.2024 23766-00020 Date of first issue: 21.10.2014

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

Viscosity, dynamic No data available

Viscosity, kinematic No data available

No data available Flow time

Explosive properties Not explosive

The substance or mixture is not classified as oxidizing. Oxidizing properties

Molecular weight No data available

Particle characteristics

Particle size No data available

Section 10: Stability and reactivity

Reactivity Not classified as a reactivity hazard. Stable under normal conditions. Chemical stability Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes 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/kgApplication 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 2.2 28.09.2024 23766-00020 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

Chronic toxicity

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.



Sugammadex Formulation

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

 2.2
 28.09.2024
 23766-00020
 Date of first issue: 21.10.2014

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
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 28.09.2024 23766-00020 Date of first issue: 21.10.2014

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

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-

: log Pow: < -6.4

octanol/water

Mobility in soil

Components:

Sugammadex:

Distribution among environ: log Koc: 3.4



Sugammadex Formulation

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 28.09.2024 23766-00020 Date of first issue: 21.10.2014

mental compartments

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

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

Environmentally hazardous : no

IATA-DGR

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

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

IMDG-Code

Not applicable UN number Proper shipping name Not applicable Class Not applicable Not applicable Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable EmS Code 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



Sugammadex Formulation

Version Revision Date: SDS Number: Date of last issue: 26.09.2023 2.2 28.09.2024 23766-00020 Date of first issue: 21.10.2014

NZS 5433

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

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

Not applicable

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components 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

Further information

Sheet

Sources of key data used to compile the Safety Data

eC

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

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

Date format : dd.mm.yyyy

Full text of other abbreviations



Sugammadex Formulation

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

 2.2
 28.09.2024
 23766-00020
 Date of first issue: 21.10.2014

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. 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.

NZ / EN