

Sugammadex Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 2024/04/06 |
|---------|----------------|-------------|---------------------------------|
| 6.0 | 2024/09/28 | 23759-00023 | Date of first issue: 2014/10/21 |

1. PRODUCT AND COMPANY IDENTIFICATION

| Chemical product name | : | Sugammadex Formulation |
|---|---|--|
| Supplier's company name, ac Company name of supplier | | |
| 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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| lf sw Mos and dela Prot | ase of eye contact vallowed t important symptoms effects, both acute and yed ection of first-aiders es to physician | :: | 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. Get medical attention if symptoms occur. Rinse mouth thoroughly with water. None known. | |
| 5. FIREF | IGHTING MEASURES | | | |
| Suita | able extinguishing media | : | Water spray Alcohol-resistant Carbon dioxide ((Dry chemical | |
| Uns med | uitable extinguishing lia | : | None known. | |
| Spe fight | cific hazards during fire- ing | : | Exposure to com | bustion products may be a hazard to health. |
| Haz ucts | ardous combustion prod- | : | Carbon oxides | |
| Spe ods | cific extinguishing meth- | : | cumstances and Use water spray | g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do |
| | cial protective equipment refighters | : | essary. | ed breathing apparatus for firefighting if nec- tective equipment. |
| 6. ACCIE | DENTAL RELEASE MEA | SUI | RES | |
| tive | sonal precautions, protec- equipment and emer- cy procedures | : | | ling advice (see section 7) and personal pro- t recommendations (see section 8). |
| Envi | ironmontal procesutions | | Avoid release to | the environment |

| 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. |



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| - | Methods and n containment a | naterials for nd cleaning up | : | For large spills, pur ment to keep mat be pumped, store Clean up remaining bent. Local or national up posal of this mate employed in the comine which regular Sections 13 and 1 | t absorbent material. rovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. ng materials from spill with suitable absor- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements. |
| 7. HA | NDLING AND | STORAGE | | | |
| I | Handling | | | | |
| - | Technical mea | sures | : | | measures under EXPOSURE SONAL PROTECTION section. |
| | _ocal/Total ver Advice on safe | | : | practice, based or sessment | equate ventilation. ance with good industrial hygiene and safety in the results of the workplace exposure as- ent spills, waste and minimize release to the |
| | Avoidance of c Hygiene meas | | : | Oxidizing agents If exposure to che flushing systems a place. When using do no | emical is likely during typical use, provide eye and safety showers close to the working ot eat, drink or smoke. ed clothing before re-use. |
| ę | Storage | | | | |
| | Conditions for | safe storage | : | | abelled containers. ce with the particular national regulations. |
| ſ | Materials to av | roid | : | | the following product types: |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Packaging material

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

: Unsuitable material: None known.

Strong oxidizing agents

| Components CAS-No | Value type (Form of exposure) Control p ters / Cor tion stand Permissil centration | icentra- lard / ile con- |
|-------------------|---|--------------------------------|
|-------------------|---|--------------------------------|



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| Suga | ammadex | | 343306-79-6 | TWA | 300 µg/m3 (OEB 2) | Internal |
| Eng | Engineering measures | | | | especially in confined concentrations. | d areas. |
| Pers | sonal protective equipm | nent | | | | |
| Res | piratory protection | : | sure assessm | ent demonstrate | tilation is not availab es exposures outside espiratory protection. | |
| | ilter type d protection | : | Particulates ty | | | |
| | Remarks protection | : | | wing personal p | nd at the end of work protective equipment: | |
| Skin | and body protection | : | | e washed after | contact. | |
| 9. PHYSI | CAL AND CHEMICAL P | ROP | ERTIES | | | |
| Phys | sical state | : | Aqueous solu | ition | | |
| Colo | bur | : | colourless | | | |
| Odo | ur | : | odourless | | | |
| Odo | ur Threshold | : | No data avail | able | | |
| Melt | ing point/freezing point | : | No data avail | able | | |
| | ng point, initial boiling t and boiling range | : | No data avail | able | | |
| Flam | nmability (solid, gas) | : | Not applicabl | e | | |
| Flam | nmability (liquids) | : | No data avail | able | | |
| ι | er explosion limit and upp Ipper explosion limit / Up er flammability limit | oere: - : | xplosion limit / No data avail | flammability lim able | it | |
| | ower explosion limit / ower flammability limit | : | No data avail | able | | |
| Flas | h point | : | No data avail | able | | |
| Dece | omposition temperature | : | No data avail | able | | |
| рН | | : | No data avail | able | | |
| Eva | poration rate | : | No data avail | able | | |
| | | | | | | |



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| Auto | -ignition temperature | : | No data available | e |
| Visco | | : | No data available | e |
| Vi | iscosity, kinematic | : | No data available | e |
| | oility(ies) /ater solubility | : | No data available | e |
| | tion coefficient: n- nol/water | : | No data available | e |
| Vapo | our pressure | : | No data available | e |
| | ity and / or relative den ensity | sity : | 1 g/cm ³ | |
| Relat | tive vapour density | : | No data available | e |
| Flow | time | : | No data available | e |
| Explo | osive properties | : | Not explosive | |
| Oxidi | zing properties | : | The substance o | r mixture is not classified as oxidizing. |
| Mole | cular weight | : | No data available | e |
| | cle characteristics article size | : | No data available | e |

10. STABILITY AND REACTIVITY

| Reactivity Chemical stability | : | Not classified as a reactivity hazard. Stable under normal conditions. |
|-------------------------------------|---|---|
| | : | Can react with strong oxidizing agents. |
| tions | | |
| 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 | : | Inhalation |
|---------------------------------|---|--------------|
| exposure | | Skin contact |
| | | Ingestion |
| | | Eye contact |



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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 |
|---|---|---|
| | | DEQ (Mayaa) > 2.000 mg/kg |

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 |
| Assessment | : Does not cause skin sensitisation. |
| Method | : OECD Test Guideline 429 |
| Test Type Exposure routes Species Assessment Method 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 |



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| | cell mutagenicity - ssment | : Weight of evic cell mutagen. | lence does not support classification as a ger |
| | nogenicity lassified based on ava | ilable information. | |
| | oductive toxicity lassified based on ava | ilable information | |
| | oonents: | | |
| | mmadex: | | |
| | s on fertility | Fertility: NOA | oute: Intravenous injection EL Mating/Fertility: 500 mg/kg body weight nic Development: NOAEL F1: 500 mg/kg boo |
| Effect ment | s on foetal develop- | Species: Albin Application Ro Developmenta Test Type: En Species: Rabb Application Ro Developmenta | oute: Intravenous injection al Toxicity: NOAEL: 500 mg/kg body weight nbryo-foetal development |
| | | Duration of Si | oute: Intravenous injection ngle Treatment: 3 Weeks al Toxicity: LOAEL: 120 mg/kg body weight |

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Sugammadex:

| Species NOAEL | : Dog | |
|-------------------|-------------|-----|
| NOAEL | : 250 mg/l | ٨g |
| Application Route | : Intraveno | ous |
| Exposure time | : 4 Weeks | ; |



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| | | | | |
| Numb | per of exposures | : | daily | |
| Expos | | : | Rat 500 mg/kg Intravenous 4 Weeks daily | |
| - | ration toxicity lassified based on availa | ble | information. | |
| 2. ECOLO | OGICAL INFORMATION | 1 | | |
| Ecoto | oxicity | | | |
| <u>Com</u> r | oonents: | | | |
| Suga | mmadex: | | | |
| Toxici plants | ity to algae/aquatic | : | mg/l Exposure time: | kirchneriella subcapitata (green algae)): 10 72 h Test Guideline 201 |
| | | | mg/l Exposure time: | irchneriella subcapitata (green algae)): > 10 72 h Test Guideline 201 |
| Toxici icity) | ity to fish (Chronic tox- | : | Exposure time: | erio (zebra fish)): 100 mg/l 30 d Test Guideline 210 |
| | ity to daphnia and other ic invertebrates (Chron- | : | Exposure time: | a magna (Water flea)): 100 mg/l 21 d Test Guideline 211 |
| Toxici | ity to microorganisms | : | | |
| | | | | |
| II Persi | stence and degradabili | tv | | |
| | ata available | -, | | |

aircraft)



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| | | | |
| Bioa | ccumulative potential | | |
| Com | ponents: | | |
| Partit | mmadex: ion coefficient: n- ol/water | : log Pow: < -6. | 4 |
| Mobi | lity in soil | | |
| Com | ponents: | | |
| Distri | mmadex: bution among environ- al compartments | : log Koc: 3.4 | |
| | rdous to the ozone lay pplicable | er | |
| | r adverse effects ata available | | |
| 3. DISPC | SAL CONSIDERATION | NS | |
| Disp | osal methods | | |
| - | e from residues | | accordance with local regulations. |
| Conta | aminated packaging | : Empty contain dling site for re | e of waste into sewer. hers should be taken to an approved waste har ecycling or disposal. se specified: Dispose of as unused product. |
| 4. TRAN | SPORT INFORMATION | l | |
| Inter | national Regulations | | |
| UN n Prope Class Subs Packi Label | TDG umber er shipping name idiary risk ng group | Not applicable no | |
| UN/IE Prope Class Subs Packi Label | er shipping name idiary risk ng group s ng instruction (cargo | Not applicable | |



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| | ng instruction (passen- | : Not applic | cable |
| IMDG UN nu Prope Class Subsi Packi Label EmS | diary risk ng group s | Not applic | cable cable cable cable cable cable |
| Not a Natio | sport in bulk according pplicable for product as nal Regulations to section 15 for specifi | to Annex II o supplied. | of MARPOL 73/78 and the IBC Code |
| - | ial precautions for use | r | |

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





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| | | | |
| Subs | tances Subject to b | e Indicated Names | |
| | pplicable | | |
| Skin | | Ibstances for PPE Re | equirements (ISHL MO Art. 594-2) |
| Carci tions | nogenic Substance | s (Article 577-2 of the | e Occupational Health and Safety Regula- |
| | nance on Preventior pplicable | of Hazards Due to S | pecified Chemical Substances |
| | nance on Preventior pplicable | of Lead Poisoning | |
| | nance on Preventior pplicable | of Tetraalkyl Lead F | Poisoning |
| | nance on Preventior pplicable | of Organic Solvent | Poisoning |
| Subs | r cement Order of th tances) pplicable | e Industrial Safety ar | d Health Law - Attached table 1 (Dangero |
| | onous and Deleterio pplicable | us Substances Cont | rol Law |
| viron | | | s of Specific Chemical Substances in the B o the Management Thereof |
| - | Pressure Gas Safet | y Act | |
| - | psive Control Law | | |
| | el Safety Law egulated as a danger | ous good | |
| | ion Law egulated as a danger | ous good | |
| Marir | ne Pollution and Sea | Disaster Prevention | etc Law |
| Bulk t | ransportation | : Not classified | as noxious liquid substance |
| Pack | transportation | : Not classified | as marine pollutant |
| Narco | otics and Psychotro | pics Control Act | |
| Not a Speci | pplicable | aw Material (Export / I | Import Permission) Export / Import permission) |



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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

16. OTHER INFORMATION

Further information

| Sources of key data used to : | Internal technical data, data from raw material SDSs, OECD |
|-------------------------------|--|
| compile the Safety Data | eChem Portal search results and European Chemicals Agen- |
| Sheet | 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 - Trans-



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portation 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.

JP / EN