

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.



Version 6.0	Revision Date: 2024/09/28	-	DS Number: 759-00023	Date of last issue: 2024/04/06 Date of first issue: 2014/10/21
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.



Versi 6.0	on Revisi 2024/(on Date:)9/28		0S Number: 759-00023	Date of last issue: 2024/04/06 Date of first issue: 2014/10/21
-	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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Version 6.0	Revision Date: 2024/09/28		S Number: 759-00023		t issue: 2024/04/06 t issue: 2014/10/21	
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		



Sugammadex Formulation

Version 6.0	Revision Date: 2024/09/28		S Number: 759-00023	Date of last issue: 2024/04/06 Date of first issue: 2014/10/21
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



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

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



Sugammadex Formulation

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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	;



ersion .0	Revision Date: 2024/09/28		OS Number: 759-00023	Date of last issue: 2024/04/06 Date of first issue: 2014/10/21
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)



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



Version 6.0	Revision Date: 2024/09/28	SDS Number 23759-00023	
	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





ersion D	Revision Date: 2024/09/28	SDS Number: 23759-00023	Date of last issue: 2024/04/06 Date of first issue: 2014/10/21
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)



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

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-



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

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