

# **Sugammadex Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
1.20	28.09.2024	23761-00021	Date of first issue: 21.10.2014

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name

: Sugammadex Formulation

Manufacturer or supplier's details						
Company name of supplier	:	MSD				
Address	:	126 E. Lincoln Avenue				
		Rahway, New Jersey U.S.A. 07065				
Telephone	:	908-740-4000				
Emergency telephone	:	1-908-423-6000				
E-mail address	:	EHSDATASTEWARD@msd.com				
Recommended use of the chemical and restrictions on use						

#### commended use of the chemical and restrictions on use

Recommended use	: Pharmaceutical
Restrictions on use	: Not applicable

## **SECTION 2. HAZARDS 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

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.
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.



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SECTION	5. FIRE-FIGHTING ME	ASL	JRES	
Suita	ble extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
Unsu medi	iitable extinguishing a	:	None known.	
	Specific hazards during fire fighting		Exposure to comb	pustion products may be a hazard to health.
Haza ucts	ardous combustion prod-	:	Carbon oxides	
Spec ods	ific extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special protective equipment for fire-fighters		necessary.	ed breathing apparatus for firefighting if ective equipment.
SECTION	6. ACCIDENTAL RELE	AS	E MEASURES	
tive e	onal precautions, protec- equipment and emer- y procedures	:		ing advice (see section 7) and personal ent 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 barriers). 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 diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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

determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding



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		certain local or n	ational requirements.		
SECTION	7. HANDLING AND ST	ORAGE			
Technical measures			measures under EXPOSURE RSONAL PROTECTION section.		
Local	/Total ventilation		equate ventilation.		
Advic	e on safe handling	<ul> <li>Handle in accordance with good industrial hygiene and sa practice, based on the results of the workplace exposure assessment</li> <li>Take care to prevent spills, waste and minimize release to environment.</li> </ul>			
Hygiene measures:If exposure to chemical is likely during typical use, pr flushing systems and safety showers close to the wo place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.					
Cond	itions for safe storage	: Keep in properly	labeled containers.		
Mater	rials to avoid	•			

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components		CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis	
Sugammadex		343306-79-6	TWA	300 µg/m3 (OEB 2)	Internal	
Engineering measures	:			especially in confinec concentrations.	l areas.	
Personal protective equip	ment					
Respiratory protection	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended 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.				

Color



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Odo	r	:	odorless	
Odo	r Threshold	:	No data available	)
pН		:	No data available	)
Melt	ing point/freezing point	:	No data available	)
Initia rang	al boiling point and boiling Je	:	No data available	
Flas	Flash point		No data available	)
Eva	Evaporation rate		No data available	)
Flan	nmability (solid, gas)	:	Not applicable	
Flan	nmability (liquids)	:	No data available	)
	er explosion limit / Upper mability limit	:	: No data available	
	er explosion limit / Lower mability limit	:	No data available	
Vap	or pressure	:	No data available	)
Rela	ative vapor density	:	No data available	)
Den	sity	:	1 g/cm <sup>3</sup>	
	ibility(ies) Vater solubility	:	No data available	)
	ition coefficient: n-	:	No data available	)
	nol/water pignition temperature	:	No data available	)
Dec	omposition temperature	:	No data available	9
	osity /iscosity, dynamic	:	No data available	9
V	iscosity, kinematic	:	No data available	)
Flow	<i>i</i> time	:	No data available	)
Expl	osive properties	:	Not explosive	
Oxic	lizing properties	:	The substance of	mixture is not classified as oxidizing.
Mole	ecular weight	:	No data available	



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	cle characteristics cle size	:	No data availab	le
SECTION	10. STABILITY AND RE	EAC	TIVITY	
Possi tions Cond Incon	nical stability ibility of hazardous reac- itions to avoid npatible materials rdous decomposition	:	Stable under no Can react with s None known. Oxidizing agent	s a reactivity hazard. ormal conditions. strong oxidizing agents. s lecomposition products are known.
SECTION	11. TOXICOLOGICAL I	NFO	ORMATION	
Inhala Skin Inges Eye c <b>Acut</b> a Not c	contact ition contact <b>e toxicity</b> lassified based on availa			
	ponents: mmadex:			
Acute	e toxicity (other routes of nistration)	:	LD50 (Rat): > 2, Application Rout LD50 (Mouse): > Application Rout	e: Intravenous > 2,000 mg/kg
-	corrosion/irritation lassified based on availa	ble	information.	
	ous eye damage/eye irri lassified based on availa			
Resp	iratory or skin sensitiz	atio	n	
• • • • • • • • • • • • • • • • • • • •	sensitization lassified based on availa	ble	information.	
-	iratory sensitization lassified based on availa	ble	information.	

## Components:

## Sugammadex:

:	Local lymph node assay (LLNA)
:	Dermal
:	Mouse
:	Does not cause skin sensitization.
	:



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	Method Result		OECD Test Guideline 429 negative		
Not c	a <b>cell mutagenicity</b> lassified based on availa ponents:	ble	information.		
-	mmadex: toxicity in vitro	:	Test Type: Bacter Method: OECD T Result: negative	ial reverse mutation assay (AMES) est Guideline 471	
				nosome aberration test in vitro an lymphoblastoid cells	
Geno	Genotoxicity in vivo : Test Type: Micronucleus test Species: Rat Result: negative		nucleus test		
	Germ cell mutagenicity -		Weight of evidence does not support classification as a germ cell mutagen.		
<b>Repr</b> Not c	lassified based on availa oductive toxicity lassified based on availa ponents:				
	mmadex:				
-	is on fertility	:	Fertility: NOAEL	: Intravenous injection /lating/Fertility: 500 mg/kg body weight Development: NOAEL F1: 500 mg/kg body	
Effect	s on fetal development	:	Species: Albino ra Application Route	ro-fetal development at : Intravenous injection pxicity: NOAEL: 500 mg/kg body weight	
			Species: Rabbit Application Route Developmental To	ro-fetal development : Intravenous injection oxicity: NOAEL F1: 200 mg/kg body weight city.: NOAEL F1: 200 mg/kg body weight	
			Duration of Single	opment : Intravenous injection e Treatment: 3 Weeks oxicity: LOAEL: 120 mg/kg body weight	
			6 / 10	SAIDILY. LOALE. 120 HIG/NG DOUY WEIGHT	



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Toxicity to daphnia and other : aquatic invertebrates (Chron-

Toxicity to microorganisms

ic toxicity)

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			Target Organs: T	eeth
Not	DT-single exposure classified based on availa	able	information.	
	<b>DT-repeated exposure</b> classified based on availa	able	information.	
Rep	peated dose toxicity			
<u>Cor</u>	nponents:			
Sug	jammadex:			
NO App Exp	ecies AEL dication Route hosure time nber of exposures	:	Dog 250 mg/kg Intravenous 4 Weeks daily	
NO App Exp	ecies AEL vlication Route vosure time nber of exposures	: : : : : : : : : : : : : : : : : : : :	Rat 500 mg/kg Intravenous 4 Weeks daily	
-	biration toxicity classified based on availa	able	information.	
SECTIO	N 12. ECOLOGICAL INF	ORN	ATION	
Eco	otoxicity			
Cor	nponents:			
Sug	gammadex:			
	icity to algae/aquatic	:	mg/l Exposure time: 7	irchneriella subcapitata (green algae)): 10 2 h <sup>-</sup> est Guideline 201
			mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 100 2 h <sup>-</sup> est Guideline 201
Tox icity	icity to fish (Chronic tox-	:	Exposure time: 3	io (zebra fish)): 100 mg/l 0 d Test Guideline 210

Method: OECD Test Guideline 210

Method: OECD Test Guideline 211

Exposure time: 21 d

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NOEC: 100 mg/l

:

NOEC (Daphnia magna (Water flea)): 100 mg/l



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			Exposure time: 30 Test Type: Respi Method: OECD T	
			EC50: > 100 mg/ Exposure time: 30 Test Type: Respi Method: OECD T	0 min
	tence and degradabi	lity		
	a available			
Bioaco	cumulative potential			
<u>Comp</u>	onents:			
Partitic	nmadex: on coefficient: n- I/water	:	log Pow: < -6.4	
Mobili	ty in soil			
<u>Comp</u>	onents:			
Distrib	nmadex: ution among environ- compartments	:	log Koc: 3.4	
Other	adverse effects			
No dat	a available			
SECTION 1	3. DISPOSAL CONSI	DEF	RATIONS	
Dispo	sal methods			

## **SECTION 14. TRANSPORT INFORMATION**

## **International Regulations**

### UNRTDG

Not regulated as a dangerous good

## IATA-DGR

Not regulated as a dangerous good

## IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.



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Dom	Domestic regulation							
	NOM-002-SCT Not regulated as a dangerous good							
-	ial precautions for us	er						
SECTION	SECTION 15. REGULATORY INFORMATION							
	Safety, health and environmental regulations/legislation specific for the substance or mixture							
esse	Federal Law for the control of chemical precursors, : Hydrochloric acid essential chemical products and machinery for producing capsules, tablets and pills.							
	The ingredients of this product are reported in the following inventories: AICS : not determined							
DSL		: not determined	t					

IECSC : not determined

## **SECTION 16. OTHER INFORMATION**

Revision Date	:	28.09.2024
Date format	:	dd.mm.yyyy

### 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 Substanc-



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es; (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

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Material Safety		eChem Portal search results and European Chemicals Agen-
Data Sheet		cy, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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