#### SAFETY DATA SHEET



## Sugammadex Formulation

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1. PRO	DUCT AND COMPANY IDI	ENT	IFICATION	
Pr	oduct name	:	Sugammadex Fo	ormulation
Ма	anufacturer or supplier's c	letai	ils	
Co	ompany	:	MSD	
Ac	ldress	:		venue rsey U.S.A. 07065
Te	lephone	:	908-740-4000	
Er	nergency telephone number	r:	1-908-423-6000	
E-	mail address	:	EHSDATASTEW	/ARD@msd.com
Re	ecommended use of the cl	nem	ical and restriction	ons on use
	ecommended use estrictions on use	:	Pharmaceutical Not applicable	

#### 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 which do not result in classification

None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Sugammadex	343306-79-6	>= 10 -< 30

#### 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 swal		:	Flush eyes with y Get medical atte If swallowed, DC Get medical atte Rinse mouth tho	ntion if symptoms occur. water as a precaution. ntion if irritation develops and persists. NOT induce vomiting. ntion if symptoms occur. roughly with water.
and ef delaye Protec	mportant symptoms fects, both acute and ed tion of first-aiders to physician	:		nutions are necessary for first aid responders tically and supportively.
. FIREFIG	HTING MEASURES			
	le extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide ( Dry chemical	
Unsuit media	able extinguishing	:	None known.	
Specif fighting	ic hazards during fire- a	:	Exposure to com	bustion products may be a hazard to health.
	dous combustion prod-	:	Carbon oxides	
Specif ods	ic extinguishing meth-	:	cumstances and Use water spray Remove undama so.	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to c
	al protective equipment fighters	:	essary.	ned breathing apparatus for firefighting if neo
. ACCIDE	NTAL RELEASE MEA	SUF	RES	
tive ec	nal precautions, protec- juipment and emer- procedures	:		lling advice (see section 7) and personal pro nt recommendations (see section 8).
Enviro	nmental precautions	:	Prevent further le Prevent spreadir barriers). Retain and dispo	the environment. eakage or spillage if safe to do so. ng over a wide area (e.g. by containment or o ose of contaminated wash water. should be advised if significant spillages ned.
	ds and materials for nment and cleaning up	:	For large spills, p ment to keep ma	rt absorbent material. provide dyking or other appropriate contain- iterial from spreading. If dyked material can e recovered material in appropriate containe
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		bent. Local or nat posal of this employed in mine which Sections 13	maining materials from spill with suitable absor- ional regulations may apply to releases and dis- material, as well as those materials and items the cleanup of releases. You will need to deter- regulations are applicable. and 15 of this SDS provide information regarding or national requirements.
7. HANDI	ING AND STORAGE		
Tech	nical measures	0	ering measures under EXPOSURE
Loca	I/Total ventilation	••••=•	h adequate ventilation.
Advid	ce on safe handling	: Handle in ac practice, bas sessment	ccordance with good industrial hygiene and safety sed on the results of the workplace exposure as- o prevent spills, waste and minimize release to the
Cond	ditions for safe storage		perly labelled containers. ordance with the particular national regulations.
Mate	rials to avoid		with the following product types:

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components 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	Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.						
Personal protective equipment							
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	Particulates type						
Hand protection							
Remarks	Wash hands before breaks and at the end of workday.						
Eye protection	Wear the following personal protective equipment: Safety glasses						
	Skin should be washed after contact. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work-						



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				do not eat, drink or smoke. ninated clothing before re-use.	
9. PHYS	SICAL AND CHEMICAL F	PROF	PERTIES		
App	bearance	:	Aqueous so	lution	
Col	our	:	colourless		
Od	our	:	odourless		
Od	our Threshold	:	No data ava	ilable	
pН		:	No data ava	ilable	
Me	lting point/freezing point	:	No data ava	ilable	
			N. J.	9-11-	

•		
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/cm <sup>3</sup>
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n- octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available

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Vis	cosity, kinematic	:	No data availabl	e
Flow t	ime	:	No data availabl	e
Explo	sive properties	:	Not explosive	
Oxidiz	ing properties	:	The substance c	r mixture is not classified as oxidizing.
Molec	ular weight	:	No data availabl	e
Partic	le size	:	No data availabl	e
. STABI	LITY AND REACTIVITY	,		
Possil tions Condi Incom Hazar produce . TOXIC Inform expose Acute Not cla	ical stability bility of hazardous reac- tions to avoid patible materials dous decomposition cts <b>OLOGICAL INFORMAT</b> nation on likely routes of	:	Stable under not Can react with s None known. Oxidizing agents No hazardous de Inhalation Skin contact Ingestion Eye contact	trong oxidizing agents.
	mmadex:			
Acute	toxicity (other routes of istration)	:	LD50 (Rat): > 2,0 Application Route	
			LD50 (Mouse): > Application Route	
-	corrosion/irritation assified based on availa	ble	information.	
Serio	us eye damage/eye irri assified based on availa	tati	on	



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#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

#### Sugammadex:

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 - : 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.

#### 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



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Effec ment	ts on foetal develop-	Species: Albin Application R Development Test Type: Er Species: Rab Application R Development Embryo-foeta Test Type: De Species: Rat Application R Duration of Si	oute: Intravenous injection al Toxicity: NOAEL: 500 mg/kg body weight nbryo-foetal development bit oute: Intravenous injection al Toxicity: NOAEL F1: 200 mg/kg body weight I toxicity: NOAEL F1: 200 mg/kg body weight evelopment oute: Intravenous injection ingle Treatment: 3 Weeks al Toxicity: LOAEL: 120 mg/kg body weight
	<b>Γ - single exposure</b> lassified based on avail	able information.	
Not c	<b>F - repeated exposure</b> lassified based on avail	able information.	
-	ated dose toxicity ponents:		
	immadex:		
Spec NOA Appli Expo	ies	: Dog : 250 mg/kg : Intravenous : 4 Weeks : daily	
Expo		: Rat : 500 mg/kg : Intravenous : 4 Weeks : daily	

#### Aspiration toxicity

Not classified based on available information.

#### **12. ECOLOGICAL INFORMATION**

#### Ecotoxicity

#### Components:

Sugammadex:



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Toxicity plants	/ 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
Toxicity icity)	/ to fish (Chronic tox-	:	Exposure time:	erio (zebra fish)): 100 mg/l 30 d Test Guideline 210
	/ to daphnia and other invertebrates (Chron- ity)		NOEC (Daphnia magna (Water flea)): 100 mg/l Exposure time: 21 d Method: OECD Test Guideline 211	
Toxicity	/ to microorganisms	:		/l 30 min piration inhibition Test Guideline 209
No data	tence and degradabili a available	ity		
	umulative potential			
Sugam	nmadex: n coefficient: n-	:	log Pow: < -6.4	
Mobilit	y in soil			
<u>Compo</u>	onents:			
Distribu	madex: ution among environ- compartments	:	log Koc: 3.4	
	adverse effects a available			



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#### **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.

#### 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
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		
UN number	:	Not applicable

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

#### Special precautions for user

Not applicable



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#### **15. REGULATORY INFORMATION**

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances
Hazardous to Health

Hazardous substances that must be registered	:	Not applicable
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#### Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

# Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

#### **16. OTHER INFORMATION**

Revision Date	:	2023/09/26
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 Agen- cy, http://echa.europa.eu/
Date format	:	yyyy/mm/dd



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#### 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 - 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.

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