

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
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#### **SECTION 1:** Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Sugammadex Formulation
1.2	Relevant identified uses of th	e s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture		Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Kilsheelan Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	E-mail address of person	:	EHSDATASTEWARD@msd.com

#### **1.4 Emergency telephone number**

responsible for the SDS

+1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.



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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Substances with a workplace exposure	e limit :		
Sugammadex	343306-79-6		>= 10 - < 20

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

Protection of first-aiders	:	No special precautions are necessary for first aid responders.
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.

#### 4.2 Most important symptoms and effects, both acute and delayed

None known.

# **4.3 Indication of any immediate medical attention and special treatment needed** Treatment : Treat symptomatically and supportively.



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#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing	g media :	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguish media	ning :	None known.
5.2 Special hazards arisi	ing from the	e substance or mixture
Specific hazards duri fighting	ng fire- :	Exposure to combustion products may be a hazard to health.
Hazardous combustic ucts	on prod- :	Carbon oxides
5.3 Advice for firefighter	S	
Special protective eq	uipment :	Wear self-contained breathing apparatus for firefighting if nec-

# 5

Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if nec- essary. Use personal protective equipment.
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.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal processions, protective equipment and emergency procedures

6.1 Personal precautions, protec	tive	e equipment and emergency procedures
Personal precautions	:	Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
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

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Soak up with inert absorbent material.
		For large spills, provide dyking or other appropriate contain-
		ment to keep material from spreading. If dyked material can

cannot be contained.



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		Clean up rema bent. Local or natior posal of this m employed in th mine which re Sections 13 ar	tore recovered material in appropriate container. aining materials from spill with suitable absor- nal regulations may apply to releases and dis- naterial, as well as those materials and items ne cleanup of releases. You will need to deter- gulations are applicable. Ind 15 of this SDS provide information regarding r national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

#### **SECTION 7: Handling and storage**

7.1 Precautions for safe handling				
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 assessment Take care to prevent spills, waste and minimize release to the			
Hygiene measures :	environment. 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 contami- nated clothing before re-use.			
7.2 Conditions for safe storage, including any incompatibilities				
Requirements for storage : areas and containers	Keep in properly labelled containers. Store in accordance with the particular national regulations.			
Advice on common storage :	Do not store with the following product types: Strong oxidizing agents Gases			
7.3 Specific end use(s)				
Specific use(s) :	No data available			

# SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sugammadex	343306-79- 6	TWA	300 µg/m3 (OEB 2)	Internal

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### 8.2 Exposure controls

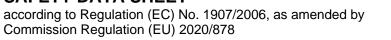
**Engineering measures** 

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.								
Personal protective equipr	Personal protective equipment							
Eye/face protection	: Wear the following personal protective equipment: Safety glasses							
Hand protection	Equipment should conform to NS EN 166 Hand protection							
Remarks	: Wash hands before breaks and at the end of workday.							
Skin and body protection	: Skin should be washed after contact.							
Respiratory protection	<ul> <li>If adequate local exhaust ventilation is not available or e sure assessment demonstrates exposures outside the re ommended guidelines, use respiratory protection.</li> <li>Equipment should conform to NS EN 143</li> </ul>	•						
Filter type	Particulates type (P)							

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state	:	Aqueous solution
Colour	:	colourless
Odour	:	odourless
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	No data available
Auto-ignition temperature	:	No data available





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	Decom	position temperature	:	No data available	9
l	рН		:	No data available	e
,	Viscos Viso	ity cosity, dynamic	:	No data available	9
	Vise	cosity, kinematic	:	No data available	e
	Flow ti	me	:	No data available	9
:		ity(ies) ter solubility	:	No data available	e
		n coefficient: n- I/water	:	No data available	e
,	Vapou	r pressure	:	No data available	9
	Density		:	1 g/cm <sup>3</sup>	
	Relativ	e vapour density	:	No data available	9
		e characteristics ticle size	:	No data available	9
9.2 C	Other ii	nformation			
	Explos	ives	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapo	ration rate	:	No data available	9
	Molecu	ılar weight	:	No data available	e
SEC		10: Stability and re	activ	vity	

10.1	l <b>Reactivity</b> Not classified as a reactivity haza	arc	i.
10.2	2 Chemical stability Stable under normal conditions.		
10.3	B Possibility of hazardous reaction Hazardous reactions :		<b>1s</b> Can react with strong oxidizing agents.
10.4	Conditions to avoid :		None known.



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#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### **10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

#### **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

#### Acute toxicity

Not classified based on available information.

#### **Components:**

#### Sugammadex:

Acute toxicity (other routes of :	LD50 (Rat): > 2.000 mg/kg
administration)	Application Route: Intravenous

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
Result	:	negative

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		<b>cell mutagenicity</b> assified based on availa	able	information.			
	<u>Comp</u>	onents:					
	Sugan	nmadex:					
	Genote	oxicity in vitro	:	Test Type: Bacter Method: OECD To Result: negative	ial reverse mutation assay (AMES) est Guideline 471		
					osome aberration test in vitro an lymphoblastoid cells		
	Genote	oxicity in vivo	:	Test Type: Micror Species: Rat Result: negative	ucleus test		
	Germ sessm	cell mutagenicity- As- ent	:	Weight of evidenc	e does not support classification as a germ		
		nogenicity assified based on availa	able	information.			
	Reproductive toxicity Not classified based on available information.						
	Comp	onents:					
	Sugan	nmadex:					
	Effects	s on fertility	:	Fertility: NOAEL	: Intravenous injection /lating/Fertility: 500 mg/kg body weight Development: NOAEL F1: 500 mg/kg body		
	Effects ment	s on foetal develop-	:	Species: Albino ra Application Route	o-foetal development at : Intravenous injection oxicity: NOAEL: 500 mg/kg body weight		
				Species: Rabbit Application Route Developmental To	o-foetal development : Intravenous injection oxicity: NOAEL F1: 200 mg/kg body weight icity: NOAEL F1: 200 mg/kg body weight		
				Duration of Single	: Intravenous injection Treatment: 3 Weeks oxicity: LOAEL: 120 mg/kg body weight		

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### 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.

#### 11.2 Information on other hazards

#### Endocrine disrupting properties

#### Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### **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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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			Exposure time: 7 Method: OECD 1	72 h Test Guideline 201
Toxic	to microorganisms	:	NOEC : 100 mg/ Exposure time: 3 Test Type: Resp Method: OECD 1	30 min
			EC50 : > 100 mg Exposure time: 3 Test Type: Resp Method: OECD 1	80 min
Toxic icity)	ity to fish (Chronic tox-	:	NOEC: 100 mg/l Exposure time: 3 Species: Danio r Method: OECD 1	30 d
	tity to daphnia and other tic invertebrates (Chron- icity)			
12.2 Pers	istence and degradabil	lity		
No da	ata available			
12.3 Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	ammadex: tion coefficient: n- nol/water	:	log Pow: < -6,4	
12.4 Mob	ility in soil			
<u>Com</u>	ponents:			
Suga	ammadex:			
Distri		:	log Koc: 3,4	
12.5 Resu	ults of PBT and vPvB a	sse	ssment	
Prod	uct:			
Asse	ssment	:	to be either persi	nixture contains no components considered istent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 End	ocrine disrupting prope	ertie	s	
			-	

### Product:

Assessment

: The substance/mixture does not contain components consid-



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		REACH Article	ndocrine disrupting properties according to 57(f) or Commission Delegated regulation 0 or Commission Regulation (EU) 2018/605 at or higher.
12.7 Othe	r adverse effects		

No data available

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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**

#### 14.1 UN number or ID number

	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.2	2 UN proper shipping name		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.:	3 Transport hazard class(es)		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good



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ΙΑΤΑ		: Not regulate	ed as a dangerous good
14.4 Pack	ting group		
ADN		: Not regulate	ed as a dangerous good
ADR		: Not regulate	ed as a dangerous good
RID		: Not regulate	ed as a dangerous good
IMDO	3	: Not regulate	ed as a dangerous good
ΙΑΤΑ	(Cargo)	: Not regulate	ed as a dangerous good
ΙΑΤΑ	(Passenger)	: Not regulate	ed as a dangerous good
	ronmental hazards egulated as a dangerc	us good	
-	<b>cial precautions for u</b>	ser	
14.7 Marit	time transport in bul	c according to IMC	) instruments
Rema	arks	: Not applical	ble for product as supplied.
SECTION	N 15: Regulatory in	formation	
15.1 Safe ture	ty, health and enviro	nmental regulation	ns/legislation specific for the substance or mix-
the m	CH - Restrictions on the narket and use of certa and articles (Anne	in dangerous subs	
REAG	CH - Candidate List of ern for Authorisation (	Substances of Ver	y High : Not applicable

Concernitor Authonsation (Article 59).			
REACH - List of substances subject to authorisation	:	Not applicable	
(Annex XIV)			
Regulation (EC) on substances that deplete the ozone	:	Not applicable	
layer			
Regulation (EU) 2019/1021 on persistent organic pollu-	:	Not applicable	
tants (recast)			
Regulation (EU) No 649/2012 of the European Parlia-	:	Not applicable	
ment and the Council concerning the export and import			
of dangerous chemicals			
5			

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable

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

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



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#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

:

#### **SECTION 16: Other information**

Other information

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

#### Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

#### **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 Agency, http://echa.europa.eu/

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



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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.

NO / EN