

Commission Regulation (EU) 2020/878

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014

### **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	ne 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 Innishannon County Cork - Ireland
	Telephone	:	353 214329300
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

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.



Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014

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 workpla	ce exposure limit :		
Sugammadex	343306-79-6		>= 10 - < 20
-			
For explanation of abbrevic	tions and anotion 16	•	•

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.



Commission Regulation (EU) 2020/878

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014

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

### 5.1 Extinguishing media

Sui	table extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Uns	suitable extinguishing dia	:	None known.
5.2 Spe	cial hazards arising from	the	e substance or mixture
	ecific hazards during fire- ting	:	Exposure to combustion products may be a hazard to health.
Haz	zardous combustion prod- s	:	Carbon oxides

### 5.3 Advice for firefighters

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 precautions, protect	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 cannot be contained.

#### 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



# Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014
		Clean up rema bent. Local or nation posal of this m employed in th mine which reg Sections 13 ar	ore recovered material in appropriate container. and a spill with suitable absor- nal regulations may apply to releases and dis- aterial, as well as those materials and items be cleanup of releases. You will need to deter- gulations are applicable. Ind 15 of this SDS provide information regarding releases.

### 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



# **Sugammadex Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014

#### 8.2 Exposure controls

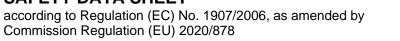
**Engineering measures** 

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.						
Personal protective equip						
Eye/face protection	Wear the following personal protective equisatety glasses	lipment:				
Hand protection	Equipment should conform to I.S. EN 166					
Remarks	Wash hands before breaks and at the end	of workday.				
Skin and body protection	Skin should be washed after contact.					
Respiratory protection	If adequate local exhaust ventilation is not sure assessment demonstrates exposures ommended guidelines, use respiratory pro Equipment should conform to I.S. EN 143	outside the rec-				
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





# Sugammadex Formulation

Vers 3.6	ion	Revision Date: 26.09.2023	-	S Number: 755-00023	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
	Decom	position temperature	:	No data available	e
	рН		:	No data available	e
	Viscos Viso	ity cosity, dynamic	:	No data available	e
	Vise	cosity, kinematic	:	No data available	9
	Flow ti	me	:	No data available	e
		ity(ies) ter solubility	:	No data available	e
		on coefficient: n- I/water	:	No data available	9
	Vapou	r pressure	:	No data available	9
	Density	y	:	1 g/cm <sup>3</sup>	
	Relativ	e vapour density	:	No data available	9
		e characteristics ticle size	:	No data available	e
9.2 C	Other i	nformation			
	Explos	ives	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapo	ration rate	:	No data available	e
	Molecu	ular weight	:	No data available	e
SEC		10: Stability and re	activ	vity	

<b>10.1 Reactivity</b> Not classified as a reactivity haza	ard.
<b>10.2 Chemical stability</b> Stable under normal conditions.	
<b>10.3 Possibility of hazardous react</b> Hazardous reactions	ions Can react with strong oxidizing agents.
<b>10.4 Conditions to avoid</b> Conditions to avoid :	None known.



# **Sugammadex Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014

#### 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



# **Sugammadex Formulation**

Version 3.6	Revision Date: 26.09.2023		DS Number: 9755-00023	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
	cell mutagenicity			
Not cla	assified based on availa	able	information.	
<u>Comp</u>	oonents:			
Sugar	mmadex:			
Genot	toxicity in vitro	:		rial reverse mutation assay (AMES) Test Guideline 471
				nosome aberration test in vitro nan lymphoblastoid cells
Genot	toxicity in vivo	:	Test Type: Micro Species: Rat Result: negative	nucleus test
Germ sessm	cell mutagenicity- As- nent	:	Weight of eviden cell mutagen.	ce does not support classification as a germ
	<b>nogenicity</b> assified based on availa	able	information.	
Repro	oductive toxicity assified based on availa			
Comp	oonents:			
Sugar	mmadex:			
-	s on fertility	:	Fertility: NOAEL	e: Intravenous injection Mating/Fertility: 500 mg/kg body weight Development: NOAEL F1: 500 mg/kg body
Effects ment	s on foetal develop-	:	Species: Albino r Application Route	yo-foetal development at e: Intravenous injection oxicity: NOAEL: 500 mg/kg body weight
			Species: Rabbit Application Route Developmental T	yo-foetal development e: Intravenous injection oxicity: NOAEL F1: 200 mg/kg body weight kicity: NOAEL F1: 200 mg/kg body weight
			Duration of Single	e: Intravenous injection e 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



# Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014

### 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



# **Sugammadex Formulation**

Version 3.6	Revision Date: 26.09.2023		OS Number: 755-00023	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
			Exposure time: 72 Method: OECD T	2 h Test Guideline 201
Toxicity	to microorganisms	:	NOEC : 100 mg/l Exposure time: 30 Test Type: Respi Method: OECD T	0 min
			EC50 : > 100 mg/ Exposure time: 30 Test Type: Respi Method: OECD T	0 min
Toxicity icity)	to fish (Chronic tox-	:	NOEC: 100 mg/l Exposure time: 30 Species: Danio re Method: OECD T	
	to daphnia and other invertebrates (Chron- ty)	:		1 d a magna (Water flea) rest Guideline 211
12.2 Persist	ence and degradabil	ity		
No data	available			
12.3 Bioacc	umulative potential			
<u>Compo</u>	nents:			
-	madex: n coefficient: n- /water	:	log Pow: < -6.4	
12.4 Mobilit	y in soil			
<u>Compo</u>	nents:			
Distribu		:	log Koc: 3.4	
	compartments s of PBT and vPvB as		oment	
		556	ssment	
Produc Assessi		:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Endoci	rine disrupting prope	ertie	s	

# Product:

Assessment

: The substance/mixture does not contain components consid-



# **Sugammadex Formulation**

Version 3.6	Revision Date: 26.09.2023	SDS Number: 23755-00023	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014		
		REACH Ar (EU) 2017/	ve endocrine disrupting properties according to ticle 57(f) or Commission Delegated regulation /2100 or Commission Regulation (EU) 2018/605 at 1% or higher.		
	r adverse effects ata available				
SECTION	N 13: Disposal cons	iderations			
13.1 Wast	te treatment methods	i			
Produ	uct aminated packaging	According are not pro Waste cod discussion Do not disp : Empty con dling site fo	in accordance with local regulations. to the European Waste Catalogue, Waste Codes duct specific, but application specific. es should be assigned by the user, preferably in with the waste disposal authorities. bose of waste into sewer. tainers should be taken to an approved waste han- or recycling or disposal. wise specified: Dispose of as unused product.		
SECTION	N 14: Transport info	ormation			
14.1 UN n	umber or ID number				
ADN		: Not regulat	ted as a dangerous good		
ADR		: Not regulat	ted as a dangerous good		
RID		: Not regulat	: Not regulated as a dangerous good		
IMDO	3	: Not regulat	ted as a dangerous good		
ΙΑΤΑ		: Not regulat	ted as a dangerous good		
14.2 UN p	roper shipping name	•			
ADN		: Not regulat	ted as a dangerous good		

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
ADN ADR	:	Not regulated as a dangerous good Not regulated as a dangerous good
	: : :	
ADR	: : :	Not regulated as a dangerous good
ADR RID		Not regulated as a dangerous good Not regulated as a dangerous good



# Sugammadex Formulation

Version 3.6	Revision Date: 26.09.2023	SDS Number: 23755-00023	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
14.4 Pack	ing group		
ADN		: Not regulated a	as a dangerous good
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	i	: Not regulated as a dangerous good	

# IATA (Passenger) : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

IATA (Cargo)

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks

: Not applicable for product as supplied.

: Not regulated as a dangerous good

### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 1005/2009 on substances that de-	:	Not applicable
plete the ozone layer Regulation (EU) 2019/1021 on persistent organic pollu-	:	Not applicable
tants (recast) Regulation (EC) No 649/2012 of the European Parlia-	:	Not applicable
ment and the Council concerning the export and import of dangerous chemicals		
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Seveso III: Directive 2012/18/ELL of the European Parliar	nent	and of the Council

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



# Sugammadex Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014

#### 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 H-Statements**

#### 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

compile the Safety Data Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/



Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
3.6	26.09.2023	23755-00023	Date of first issue: 21.10.2014

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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