According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



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SECTION 1: Identification of the substance/mixture and of the company/undertaking

Trade name

: Sugammadex Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-	: Pharmaceutical
stance/Mixture	

1.3 Details of the supplier of the safety data sheet

Company	:	MSD Kilsheelan . Clonmel Tipperary, IE
Telephone	:	353-51-601000
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

National Poison Control Center (UZEM): 114 Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848 Not a hazardous substance or mixture.

2.2 Label elements

Labelling T.R. SEA No 28848

Not a hazardous substance or mixture.

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		

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				Registra ber	ation num-		
Ī	Substar	nces with a workpla	ce exposure	limit :		·	
	Sugamr	nadex		343306-	-79-6		>= 10 - < 20
L	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.

SECTION 5: Firefighting measures

5.1	Extinguishing media Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
	Unsuitable extinguishing media	:	None known.
5.2	Special hazards arising from Specific hazards during fire- fighting		e substance or mixture Exposure to combustion products may be a hazard to health.
	Hazardous combustion prod- ucts	:	Carbon oxides

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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, protective equipment and emergency procedures

Personal precautions	:	Follow safe handling advice and personal protective equip-
		ment recommendations.

6.2 Environmental precautions

Environmental precautions	:	Discharge into the environment must be avoided. 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.
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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 be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent.
		Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or 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

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Advice	Total ventilation e on safe handling ne measures	:	 CONTROLS/PERSONAL PROTECTION section. Use only with adequate ventilation. Handle in accordance with good industrial hygiene and sa practice, based on the results of the workplace exposure a sessment Take care to prevent spills, waste and minimize release to environment. If exposure to chemical is likely during typical use, provide flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contanated clothing before re-use. 	
7.2 Condit	ions for safe storage,	inc	luding any incom	patibilities
•	rements for storage and containers	:	Keep in properly the particular nat	labelled containers. Store in accordance with ional regulations.
Advice	e on common storage	:	Do not store with Strong oxidizing	the following product types: agents
-	i c end use(s) fic 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	200 µg/m3	Internal

8.2 Exposure controls

Engineering measures

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Personal protective equipm	ent	
Eye protection	:	Wear the following personal protective equipment: Safety glasses Equipment should conform to TS EN 166
Hand protection		
Remarks Skin and body protection Respiratory protection		Wash hands before breaks and at the end of workday. Skin should be washed after contact. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to TS EN 143

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Fil	lter type	: Particulates typ	be (P)
SECTION 9: Physical and chemical properties			

9.1 Information on basic physical and chemical properties

information on basic physical	an	a chemical properti
Appearance	:	Aqueous solution
Colour	:	colourless
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available
range Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
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/cm3
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-	:	No data available
octanol/water		
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available
Explosive properties	:	Not explosive

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Oxic	lizing properties	: The substance	e or mixture is not classified as oxidizing.
	r information nmability (liquids)	: No data availa	able
Mole	ecular weight	: No data available	
Part	icle size	: No data availa	able

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

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 toxicological effects

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 administration)	:	LD50 (Rat): > 2.000 mg/kg Application Route: Intravenous

LD50 (Mouse): > 2.000 mg/kg Application Route: Intravenous

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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

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- As- : sessment	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.

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Com	ponents:				
-	ammadex:	On a land Date			
Effects on fertility :		Application Ro Fertility: NOA	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		
ment		Species: Albin Application Ro	nbryo-foetal development lo rat bute: Intravenous injection al Toxicity: NOAEL: 500 mg/kg body weight		
		Species: Rabb Application Ro Teratogenicity Developmenta	nbryo-foetal development bit oute: Intravenous injection r: NOAEL: 200 mg/kg body weight al Toxicity: NOAEL F1: 200 mg/kg body weight toxicity: NOAEL F1: 200 mg/kg body weight		
		Duration of Si	oute: Intravenous injection ngle Treatment: 3 Weeks al Toxicity: LOAEL: 120 mg/kg body weight		

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Sugammadex:

Species NOAEL Application Route Exposure time Number of exposures		Dog 250 mg/kg Intravenous 4 Weeks daily
Species NOAEL Application Route Exposure time Number of exposures	:	Rat 500 mg/kg Intravenous 4 Weeks daily

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Aspiration toxicity

Not classified based on available information.

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 Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms :	NOEC : 100 mg/l Exposure time: 30 min Test Type: Respiration inhibition Method: OECD Test Guideline 209
	EC50 : > 100 mg/l Exposure time: 30 min Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic tox- : icity)	NOEC: 100 mg/l Exposure time: 30 d Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210
Toxicity to daphnia and other : aquatic invertebrates (Chron- ic toxicity)	NOEC: 100 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
12.2 Persistence and degradability No data available	
12.3 Bioaccumulative potential	
Components:	

Sugammadex:

Partition coefficient: n- : log Pow: < -6,4 octanol/water

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12.4 Mobility in soil

Components:

Sugammadex:

Distribution among environ- : log Koc: 3,4 mental compartments

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other 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.
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

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : N

: Not applicable for product as supplied.

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SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, : Not applicable placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)
Regulation on Persistent Organic Pollutants (Number : Not applicable 30595)
Regulation on prevention of major industrial accidents. Reg number 30702 Not applicable

Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I". Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry. Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

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

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

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.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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 - In-

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ternational 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; 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 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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