

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 1 of 13

Section 1- Chemical Product and Company	
Marketing Authorization Holder and Address:	Tamarang, S, A. Balmes 85, 2º 08008 Barcelona Spain
Product Identifier:	Sugammadex Tamarang 100 mg/mL solution for injection
Common/Trade Name:	Sugammadex
Chemical Name:	6A,6B,6C,6D,6E,6F,6G,6H-octakis-S-(2-carboxyethyl)- 6A,6B,6C,6D,6E,6F,6G,6Hoctathio-γ-cyclodextrin octasodium salt
Chemical formula:	$C_{72}H_{104}Na_8O_{48}S_8$
Product Use:	Pharmaceutical
Molecular weight	2178
Product type:	Regulated Prescription Drug
Container Information:	Vials

Section 2 - Composition / Information on ingredients		
Substance/Mixture: mixture		
Product	CAS No.	Concentration (% w/w)
Sugammadex	343306-79-6	≥10 - <20

Section 3 - Hazards identification	
GHS classification in accordance 29 CFR 1910.1200	Not a hazardous substance or mixture
GHS label elements	Not a hazardous substance or mixture
Other hazards Fire and Explosion Health Environment Compliance with PBT/vPvB	No data available. No data available No data available See section 12
EU Classification according to Regulation (EC) No 1272/2008	Not classified

Section 4 - First Aid Measures	
Description of first aid measures	
General notes	In case of reaction described below or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison center. Show the label and this safety data sheet.
If inhaled	Remove to fresh air. If breathing becomes difficult, get medical.

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 2 of 13

Skin contact	Wash with water and soap as a precaution, flush with copious amounts of water at least for 15 minutes. Get medical attention if symptoms occur.
Eyes contact	Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes. Get medical attention if irritation develops and persists.
If swallowed/ingestion	If swallowed, DO NOT induce vomiting. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.
Self-protection of the first aider	No special precautions are necessary for first aid responders
Most important symptoms and effects, both acute and delayed	Non known
Self-protection of first-aiders	No special precautions are necessary for first aid responders
Indication of any immediate medical attention and special treatment needed:	
Medical treatment	Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information center.
Medical conditions caused or aggravated by exposure	Non known
Health surveillance procedures	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
Antidotes	No specific antidotes
Notes to Physician:	Treat symptomatically and supportively. See patient package insert in shipping carton for complete information.

Section 5 - Fire Fighting Measures	
Extinguishing media	
Suitable extinguishing media	Water spray Alcohol-resistant foam Carbondioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	Non known
Special hazards arising from the substance or mixture	
Fire and explosion hazards	Exposure to combustion products may be

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 3 of 13

	a hazard to health
Hazardous combustion products	Carbon oxides
Specific extinguishing methods	Use extinguishing measures that are appropriate to local circumstances 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.
Advice for fire-fighter	
Special protective equipment and precautions for fire-fighters	As with all fires, evacuate personnel to a safe area. Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Use water spray or fog for cooling exposed containers.

Section 6 - Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
For non-emergency personnel	Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Personnel involved in clean-up should wear appropriate personal protective (see section 8). Minimize exposure. Avoid dust generation. Spill should be handled by trained cleaning personnel. Evacuate area.
Emergency responders	Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection (see section 8).
Environmental precautions	
Environmental precautions	Discharge into the environment must be avoided. Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas. Care should be taken to avoid environmental release. If spill is outdoors, cover with plastic sheet to minimize spreading or contact with rain.
Methods and materials for containment and cleaning up	
Clean-up methods	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 4 of 13

	from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining material from spill with suitable absorbent.
Decontamination procedures	No data available

Section 7 - Handling and Storage	
Local/Total ventilation	Use only with adequate ventilation.
Precautions for safe handling	
General Requirements	Handle in accordance with good industrial hygiene and safety procedures. Use only with adequate ventilation. Use good occupational work practice. Not to eat, drink and smoke in work areas. Avoid dispersion as a dust cloud. Wash thoroughly after handling. Wash hands before breaks and at the end of workday. Skin should be washed after contact. Remove contaminated clothing and protective equipment before entering eating areas.
Ignition controls	No data available
Protective systems	No data available
Conditions for safe storage, including any incompatibilities	
Conditions for safe storage	Keep in properly labelled containers. Store in accordance with the particular national regulation.
Materials to avoid	Do not store with the following product types: strong oxidizing agents.

Section 8 - Exposure Controls/Personal Protection	
Control parameters	
Occupational Exposure Limit	No data available
DNELs and PNECs	No data available
Exposure controls /engineering controls	
Exposure controls	An Exposure Control Approach (ECA) should be established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment
Containment	Local exhaust ventilation is recommended or other engineering controls to maintain

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 5 of 13

	airborne levels below recommended exposure limits or general room ventilation. Minimize workplace exposure concentrations.
Ventilation	Ensure adequate ventilation, especially in confined areas
Administrative	Entry to the working area should be controlled. Doors with interlocks may be needed for materials airlocks and locker rooms. Only equipment and supplies necessary for job activities should be taken into working area
Personal protective equipment	
Respiratory Protection:	General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulation (29 CFR 1910.134) and use NIOSH/MSHA APPROVED RESPIRATORS. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where Air purifying respirators may not provide adequate protection. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with protection factor sufficient to control exposures to below the OEL. Follow local regulations for respirator use in the workplace. Protecting complete mask (filter P3) if sole means of protection.
Eye Protection:	Wear approved safety glasses with side shields or cover goggles if eye contact is possible
Hand protection:	Wash hands before breaks and at the end of workday. The selection of gloves for a specific

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 6 of 13

	activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must consider any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Compatible chemical-resistant gloves (e.g. PVC, neoprene, rubber).
Skin and body protection:	Skin should be washed after contact. Use protective clothing (uniforms, lab coats, disposable coveralls, etc....) in both production and laboratory areas.
Hygiene measures:	Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

Section 9 - Physical and Chemical Properties	
Appearance:	Aqueous solution
Color	colorless
Odor:	odorless Odor
Threshold:	No data available
pH:	No data available
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
Upper explosion limit	No data available
Lower explosion limit	No data available
Vapor pressure	No data available
Relative vapor density	No data available
Density	1 g/cm
Solubility(ies) Water solubility	No data available
Partition coefficient: octanol/water	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 7 of 13

Viscosity Viscosity, dynamic	No data available
Flow time	No data available
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing

Section 10 - Stability and Reactivity	
Reactivity	Not classified as a reactivity hazard
Chemical Stability:	Stable under normal conditions and handling
Incompatible materials	Oxidizing agents
Hazardous decomposition products:	No hazardous decomposition products are known.
Conditions to avoid:	None known
Possibility of hazardous reactions:	Can react with strong oxidizing agents

Section 11- Toxicological Information	
Signs & Symptoms of Exposure:	Inhalation, skin contact, ingestion and eye contact: Not classified based on available information.

11.1 Acute Toxicity

Component	Type	Route	Species	Dosage
Sugammadex	LD50	Intravenous	Rat	>2000 mg/kg
Sugammadex	LD50	Intravenous	Mouse	>2000 mg/kg

Skin corrosion/irritation	Not classified based on available information
Serious eye damage/eye irritation	Not classified based on available information
Skin sensitization	Not classified based on available information
Respiratory sensitization	Not classified based on available information

Component	Test Type	Routes of exposure	Species	Assessment	Method	Result
Sugammadex	Local lymph node assay (LLNA)	Dermal	Mouse	Does not cause skin sensitization	OECD Test Guideline 429	Negative

11.2 Germ cell mutagenicity

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 8 of 13

Not classified based on available information.

Genotoxicity in vitro:

Component	Test Type	Routes of exposure	Species	Assessment	Method	Result
Sugammadex	Bacterial reverse mutation assay (AMES)				OECD Test Guideline 471	Negative
Sugammadex	Chromosome aberration test in vitro	Human lymphoblastoid cells				Negative

Genotoxicity in vivo:

Component	Test Type	Routes of exposure	Species	Assessment	Method	Result
Sugammadex	Micronucleus test		Rat			Negative

Germ cell mutagenicity Assessment: weight of evidence does not support classification as a germ cell mutagen.

11.3 Carcinogenicity

Not classified based on available information.

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA. No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP: no ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipate carcinogen by NTP.

11.4 Reproductive toxicity

Not classified based.

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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	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 9 of 13

Effects on fetal development	Test Type: Embryo-fetal development Species: Albino rat Application Route: Intravenous injection Developmental Toxicity: NOAEL: 500 mg/kg body weight
	Test Type: Embryo-fetal development Species: Rabbit Application Route: Intravenous injection Teratogenicity: NOAEL: 200 mg/kg body weight Developmental Toxicity: NOAEL F1: 200 mg/kg body weight Embryo-fetal toxicity.: NOAEL F1: 200 mg/kg body weight
	Test Type: Development Species: Rat Application Route: Intravenous injection Duration of Single Treatment: 3 Weeks Developmental Toxicity: LOAEL: 120 mg/kg body weight Target Organs: Teeth

11.5 STOT-single exposure

Not classified based on available information.

11.6 STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

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

11.7 Aspiration toxicity

Not classified based on available information.

Section 12- Ecological information

12.1 Ecotoxicity

Toxicity to algae	NOEC (Pseudokirchneriella subcapitata (green algae)): 10 mg/l
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	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 10 of 13

	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 fish (Chronic toxicity)	NOEC (Danio rerio (zebra fish)): 100 mg/l Exposure time: 30 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	NOEC (Daphnia magna (Water flea)): 100 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
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

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: log Pow: < -6.4

12.4 Mobility in soil

Distribution among environmental compartments: log Koc: 3.4

12.5 Other adverse effects

No data available

Section 13- Disposal Considerations	
Waste from residues:	Dispose of in accordance with local regulations
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 11 of 13

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
US regulation	
49CFR	Not regulated as a dangerous good

Section 15 – Regulatory Information

REACH use authorizations: The substance is not included in the candidate list of SVHC neither on Annex XIV of REACH Regulation (authorization list).

REACH use restrictions: The substance is not subject to any restrictions stated in Annex XVII of REACH Regulation.

Chemical safety assessment: Not applicable (*).

(*) **REGULATION (EC) No 1907/2006:** The provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is used in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards

No SARA Hazards

SARA 313

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 12 of 13

Section 16- Other information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

Abbreviations and acronyms used in the safety data sheet:

RTECS number: is an identification number set by the US Registry of Toxic Effects of Chemical Substances. **LD50:** (Lethal Dose 50) is the dose of a chemical which kills 50% of a sample population. **PBT:** Persistent, bioaccumulative and toxic substance. **mPmB:** Very persistent and very accumulative substances. **DNEL:** Derived no effect level. **PNEC:** Predicted no effect concentration. **SVHC:** Substance of very high concern. **RID:** Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail). **ADR:** Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road). **ICAO:** International Civil Aviation Organization. **IATA:** International Air Transport Association. **IMDG:** International Maritime Code for Dangerous Goods. **AICS** - Australian Inventory of Chemical Substances. **ASTM** - American Society for the Testing of Materials; **bw** - Body weight; **CERCLA** - Comprehensive Environmental Response, Compensation German Institute for Standardisation; **DOT** - Department of Transportation; **DSL** - Domestic Sub-stances List (Canada); **ECx** - Concentration associated with x% response; **EHS** - Extremely Hazardous Substance; **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; **HMIS** - Hazardous Materials Identification System; **IARC** - International Agency for Research on Cancer; **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; **MSHA** - Mine Safety and Health Administration; **n.o.s.** - Not Otherwise Specified; **NFPA** - National Fire Protection Association; **NO(A)EC** - No Observed (Adverse) Effect Concentration;

	MATERIAL SAFETY DATA SHEET (MSDS)		
	Sugammadex Tamarang 100 mg/mL solution for injection		
MSDS No.: MSDS002	Version No: 01	In force since: 10/2023	Page 13 of 13

NO(A)EL - No Observed (Adverse) Effect Level; **NOELR** - No Observable Effect Loading Rate; **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; **RCRA** - Resource Conservation and Re-covery Act; **REACH** - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; **RQ** - Reportable Quantity; **SADT** - Self-Accelerating Decomposition Temperature; **SARA** - Superfund Amendments and Reauthorization Act; **SDS** - Safety Data Sheet; **TCSI** - Taiwan Chemical Sub-stance 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

Sources of key data used to compile the Material 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/>

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