SAFETY DATA SHEET



Bezlotoxumab Formulation

Version 1.18	Revision Date: 28.09.2024	-	S Number: 3179-00019	Date of last issue: 30.09.2023 Date of first issue: 22.07.2016			
SECTION	SECTION 1. IDENTIFICATION						
Prod	Product name		Bezlotoxumab F	ormulation			
Manu	ufacturer or supplier's	s detai	ils				
Com	pany	:	MSD				
Addr	ess	:		Alem St., 8 Floor rgentina C1001AFB			
Telep	ohone	:	908-740-4000				
Emei	Emergency telephone		1-908-423-6000				
E-ma	E-mail address		EHSDATASTEWARD@msd.com				
Reco	ommended use of the	chem	ical and restriction	ons on use			
	mmended use rictions on use	:	Pharmaceutical Not applicable				

SECTION 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

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: Mixture
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Components

Chemical name	CAS-No.	Concentration (% w/w)
Bezlotoxumab	1246264-45-8	>= 1 -< 5

SECTION 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.
	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.
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	important symptoms effects, both acute and	:		ntion if symptoms occur. roughly with water.			
Prote	ection of first-aiders s to physician	:	No special precautions are necessary for first aid responders. Treat symptomatically and supportively.				
SECTION	5. FIRE-FIGHTING ME	ASL	IRES				
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical				
Unsu medi	itable extinguishing a	:	None known.				
Spec fighti	ific hazards during fire ng	:	: Exposure to combustion products may be a hazard to h				
Haza ucts	rdous combustion prod-	:	Carbon oxides				
Spec ods	ific extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do			
	Special protective equipment for fire-fighters		necessary.	ned breathing apparatus for firefighting if tective equipment.			

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate



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		container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and ite employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regard certain local or national requirements.	
SECTION	7. HANDLING AND ST	TORAGE	
Tech	nical measures	•	ering measures under EXPOSURE /PERSONAL PROTECTION section.
Local	/Total ventilation	: Use only wit	h adequate ventilation.
Advic	e on safe handling	: Handle in ac practice, bas assessment	cordance with good industrial hygiene and safety sed on the results of the workplace exposure prevent spills, waste and minimize release to the
		environment	
Cond	litions for safe storage	: Keep in prop	berly labeled containers.

Conditions for sale storage	•	
		Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types:
		Strong oxidizing agents
		Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Bezlotoxumab	1246264-45- 8	TWA	5.0 mg/m3 (OEB 1)	Internal

Engineering measures :	Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip- less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.
Personal protective equipmen	t
Respiratory protection :	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type :	Particulates type

Filter type Hand protection	:	Particulates type
Material	:	Chemical-resistant gloves
Eye protection	:	Wear safety glasses with side shields or goggles.



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	and body protection ne measures	 mists or aeroso Wear a facesh potential for dir aerosols. Work uniform of If exposure to a eye flushing sy working place. When using do Wash contamin The effective o engineering co appropriate de 	chemical is likely during typical use, provide stems and safety showers close to the not eat, drink or smoke. nated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Color	:	Colorless to pale yellow
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	5,7 - 6,3
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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1,0146 g/cm ³



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Solubility(ies) Water solubility Partition coefficient: n- octanol/water		:	No data available Not applicable	9			
	toignition temperature	:	: No data available				
De	composition temperature	:	No data available				
Viscosity Viscosity, dynamic		:	1,2 mPa.s (25 °				
	Viscosity, kinematic	:	1,833 mm²/s (4	,			
Ex	plosive properties	:	1,183 mm²/s (25 Not explosive	5 °C)			
Ox	idizing properties	:	The substance o	r mixture is not classified as oxidizing.			
Мс	ecular weight	:	No data available	9			
	rticle characteristics rticle size	:	Not applicable				

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Components:

Bezlotoxumab:

Acute toxicity (other routes of	:	LD50 (Mouse): > 125 mg/kg
administration)		Application Route: Intravenous
		Remarks: No adverse effect has been observed in acute tox-
		icity tests.

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_	corrosion/irritation lassified based on av	ailable information.				
	ous eye damage/eye lassified based on av					
Resp	iratory or skin sens	itization				
-	sensitization lassified based on av	ailable information.				
-	iratory sensitization lassified based on av					
	n cell mutagenicity lassified based on av	ailable information.				
	inogenicity lassified based on av	ailable information.				
-	Reproductive toxicity Not classified based on available information.					
	STOT-single exposure Not classified based on available information.					
	F-repeated exposure lassified based on av					
Repe	ated dose toxicity					
Com	ponents:					
Spec NOAI Applie	EL cation Route sure time	: Mouse : 50 mg/kg : Intravenous : 15 d : No significant	adverse effects were reported			
	EL cation Route sure time	: Mouse : 125 mg/kg : Intravenous : 21 d : No significant	adverse effects were reported			
-	ration toxicity lassified based on av	ailable information.				

Experience with human exposure

Components:

Bezlotoxumab:

Inhalation

: Symptoms: Nausea, Headache, Diarrhea, Fever

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 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
		handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable



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The in AICS	gredients of this pro	oduct are reported in : not determined	n the following inventories:		
DSL		: not determined	Ł		
IECSC	;	: not determined	Ł		
SECTION 16. OTHER INFORMATION					

Revision Date	: 28.09.2024
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Date format	: dd.mm.yyyy
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Further information

Sources of key data used to : compile the Material Safety	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
Data Sheet	cy, http://echa.europa.eu/

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



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