



Vers 1.19		Revision Date: 28.09.2024		S Number: 005-00020	Date of last issue: 06.04.2024 Date of first issue: 22.07.2016
SEC	TION 1: Product	IDENTIFICATION	:	Bezlotoxumab Fc	ormulation
	Manufa	cturer or supplier's d	letai	ls	
	Compa	ny	:	MSD	
	Address		:	Building A - Level 1/26 Talavera Rd Macquarie Park NSW, Australia 2113	
	Telepho	one	:	1 800 033 461	
	Emerge	ency telephone number	:	Poisons Informat	ion Centre: Phone 13 11 26
	E-mail a	address	:	EHSDATASTEW	ARD@msd.com
	Recom	mended use of the ch	nemi	ical and restrictio	ons on use
		mended use ions 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 : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Bezlotoxumab	1246264-45-8	< 10

SECTION 4. FIRST AID MEASURES

If inhaled	:	If inhaled, remove to fresh air.
In case of skin contact	:	Get medical attention if symptoms occur. Wash with water and soap as a precaution.
In case of eye contact	:	Get medical attention if symptoms occur. Flush eyes with water as a precaution.
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If swallowed Most important symptoms and effects, both acute and delayed Protection of first-aiders Notes to physician		::	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water. None known.		
SEC	TION 5	. FIREFIGHTING MEA	SU	RES	
	Suitable extinguishing media		:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
	Specific fighting	c hazards during fire-	:	Exposure to comb	pustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	Carbon oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special for firef	protective equipment ighters	:	essary.	ed breathing apparatus for firefighting if nec-

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Follow safe handling advice (see section 7) and personal pro- tective 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.



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contair	ds and materials for nment and cleaning up	For large spills, p ment to keep ma be pumped, store Clean up remain bent. Local or national posal of this mat employed in the mine which regu Sections 13 and certain local or n	rt absorbent material. provide dyking or other appropriate contain- terial from spreading. If dyked material can e recovered material in appropriate container. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding ational requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures Local/Total ventilation Advice on safe handling		See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. Use only with adequate ventilation. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	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 contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Conditions for safe storage	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Components with workplace control parameters

Engineering measures

: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-



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			design and opera protect products,	ctions). ontrols should be implemented by facility ited in accordance with GMP principles to workers, and the environment. tions do not require special containment.	
Pers	sonal protective equipm	ent			
F	piratory protection ilter type d protection	:	sure assessment	exhaust ventilation is not available or expo- demonstrates exposures outside the rec- lines, use respiratory protection.	
N	laterial	:	Chemical-resistar	nt gloves	
Eye	Eye protection		Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.		
Skin	and body protection	:	Work uniform or I	aboratory coat.	
SECTION	N 9. PHYSICAL AND CHI	EMI	CAL PROPERTIE	S	
Арр	earance	:	Aqueous solution	n	
Colo	bur	:	Colorless to pale	e yellow	
Odo	ur	:	No data available	e	
Odo	ur Threshold	:	No data availabl	e	
рН		:	5.7 - 6.3		
Melt	ing point/freezing point	:	No data available	e	
Initia rang	al boiling point and boiling le	:	No data availabl	e	
Flas	h point		No data available	e	
Eva	poration rate	:	No data available	e	
Flam	nmability (solid, gas)	:	Not applicable		
Flam	nmability (liquids)	:	No data available	e	
	er explosion limit / Upper mability limit	:	No data available	e	
	er explosion limit / Lower mability limit	:	No data availabl	e	

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Vapo	our pressure	:	No data available	9
	tive vapour density	:	No data availabl	e
Rela	tive density	:	No data availabl	e
Dens	sity	:	1.0146 g/cm ³	
	bility(ies) /ater solubility	:	No data availabl	e
	tion coefficient: n-	:	Not applicable	
	nol/water -ignition temperature	:	No data available	9
Deco	omposition temperature	:	No data available	9
Visco V	osity iscosity, dynamic	:	1.2 mPa.s (25 °	C)
V	iscosity, kinematic	:	1.833 mm2/s (4	°C)
			1.183 mm2/s (2	5 °C)
Expl	osive properties	:	Not explosive	
Oxid	izing properties	:	The substance c	r mixture is not classified as oxidizing.
Mole	cular weight	:	No data available	e
	cle characteristics cle size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition	:	
products		

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation Skin contact
	Ingestion Eye contact



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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 toxicity tests.

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.

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Bezlotoxumab:

Species	:	Mouse
NOAEL	:	50 mg/kg
Application Route	:	Intravenous
Exposure time	:	15 d
Remarks	:	No significant adverse effects were reported

Species

Mouse

:





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	cation Route sure time	: 125 mg/kg : Intravenous : 21 d : No significant	adverse effects were reported
-	ration toxicity	the barrier for a second second	
	lassified based on ava		
•	ponents:	xposure	
	otoxumab:		
Inhala		: Symptoms: Na	ausea, Headache, Diarrhoea, Fever
SECTION	12. ECOLOGICAL IN	FORMATION	
	12. ECOLOGICAL IN	FORMATION	
Ecote		FORMATION	
Ecote No da Persi	oxicity		
Ecoto No da Persi No da Bioa	oxicity ata available istence and degradat	bility	
Ecote No da Persi No da Bioae No da Mobi	oxicity ata available istence and degradat ata available ccumulative potentia	bility	

Disposal me	thods
-------------	-------

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 han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	: Not a	applicable
Proper shipping name	: Not a	pplicable
Class	: Not a	pplicable
Subsidiary risk	: Not a	pplicable
Packing group	: Not a	applicable
Labels	: Not a	applicable

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Envir	onmentally hazardous	:	no	
IATA	-DGR			
UN/IE) No.	:	Not applicable	
Prope	er shipping name	:	Not applicable	
Class		:	Not applicable	
	diary risk	:	Not applicable	
	ng group	:	Not applicable	
Label	-	:	Not applicable	
Packi aircra	ng instruction (cargo ft)	:	Not applicable	
	ng instruction (passen- rcraft)	:	Not applicable	
IMDG	-Code			
UN n	umber	:	Not applicable	
Prope	er shipping name	:	Not applicable	
Class		:	Not applicable	
Subsi	diary risk	:	Not applicable	
	ng group	:	Not applicable	
Label	S	:	Not applicable	
EmS	Code	:	Not applicable	
Marin	e pollutant	:	Not applicable	
Trans	sport in bulk according	ı to	Annex II of MAR	POL 73/78 and the IBC Code
	pplicable for product as			

National Regulations

ADG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environment ture	tal regulations/legislation specific for the substance or mix-
Therapeutic Goods (Poisons :	
Standard) Instrument	publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)
Prohibition/Licensing Requirement	ts : There is no applicable prohibition, authorisation and restricted use requirements, including for carcino- gens referred to in Schedule 10 of

the model WHS Act and Regula-

tions.



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The c	omponents of this pr	oduct are reported in	the following inventories:

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

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date Sources of key data used to compile the Safety Data Sheet	:	28.09.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Date format	:	dd.mm.yyyy

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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