



Version 2.1	Revision Date: 28.09.2024		S Number: 034-00022	Date of last issue: 06.04.2024 Date of first issue: 22.07.2016	
SECTI	SECTION 1: Identification of the substance/mixture and of the company/undertaking				
1.1 Pro	duct identifier				
Tra	ade name	:	Bezlotoxumab Fo	rmulation	
1.2 Rel	evant identified uses of	the su	Ibstance or mixt	ure and uses advised against	
Us	e of the Sub- nce/Mixture		Pharmaceutical		
	commended restrictions use	:	Not applicable		
1.3 Det	ails of the supplier of the	e safe	ty data sheet		
-	mpany	:	MSD 117 16th Road	use, Midrand, South Africa	
Te	lephone	:	+27 11 655 3000		
	nail address of person ponsible for the SDS	:	EHSDATASTEW	ARD@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.



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#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Bezlotoxumab	1246264-45-8		>= 1 - < 10

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.





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<ul> <li>5.2 Special hazards arising from Specific hazards during fire- fighting</li> <li>Hazardous combustion prod- ucts</li> </ul>		:	Exposure to comb	<b>xture</b> pustion products may be a hazard to health.	
	Special for firefi	for firefighters protective equipment ghters c extinguishing meth-	:	essary. Use perso Use extinguishing cumstances and t	ed breathing apparatus for firefighting if nec- onal protective equipment. 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

### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective 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	<ul> <li>Avoid release to the environment.</li> <li>Prevent further leakage or spillage if safe to do so.</li> <li>Prevent spreading over a wide area (e.g. by containment or oil barriers).</li> <li>Retain and dispose of contaminated wash water.</li> <li>Local authorities should be advised if significant spillages cannot be contained.</li> </ul>

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up	<ul> <li>Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment 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 absorbent.</li> <li>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.</li> <li>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</li> </ul>
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#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.



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#### **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 as- sessment
	Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	<ul> <li>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.</li> <li>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.</li> </ul>

#### 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
3 Specific end use(s)		

## 7.3

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
Bezlotoxumab	1246264- 45-8	TWA	5.0 mg/m3 (OEB 1)	Internal

#### 8.2 Exposure controls

#### **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 equipment



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Eye/f	face protection	If the work er mists or aero Wear a faces	glasses with side shields or goggles. nvironment or activity involves dusty conditions, sols, wear the appropriate goggles. shield or other full face protection if there is a direct contact to the face with dusts, mists, or
	l protection aterial	: Chemical-res	istant gloves
	and body protection iratory protection	: If adequate lo sure assessm	or laboratory coat. In the second second In the second second Second second second Second second second Second second sec
Fi	lter type	: Particulates t	

### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	Aqueous solution Colorless to pale yellow No data available 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
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
Relative density	:	No data available
Density	:	1,0146 g/cm <sup>3</sup>
Solubility(ies) Water solubility Partition coefficient: n- octanol/water Auto-ignition temperature	:	No data available Not applicable No data available

### SAFETY DATA SHEET



## **Bezlotoxumab Formulation**

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De	composition temperature	: No c	lata available	e		
Vis	cosity Viscosity, dynamic	: 1,2 r	nPa.s (25 °C	C)		
	Viscosity, kinematic	: 1,83	3 mm2/s (4	°C)		
		1,18	3 mm2/s (25	5 °C)		
Ex	plosive properties	: Not	explosive			
Ox	Oxidizing properties		substance o	r mixture is not classified as oxidizing.		
9.2 Oth	er information					
Fla	mmability (liquids)	: No c	lata available	9		
Мс	Molecular weight		: No data available			
Pa	Particle size		applicable			
SECTI	ON 10: Stability and re	activity				

## 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



rsion	Revision Date: 28.09.2024	SDS Number: 809034-00022	Date of last issue: 06.04.2024 Date of first issue: 22.07.2016
Acute	e toxicity		
Not cl	assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
Bezlo	otoxumab:		
	toxicity (other routes histration)	Application Ro	: > 125 mg/kg ute: Intravenous adverse effect has been observed in acute tox
-	corrosion/irritation assified based on ava	ailable information.	
Serio	us eye damage/eye	irritation	
Not cl	assified based on ava	ailable information.	
Resp	iratory or skin sensi	itisation	
Skin	sensitisation		
Not cl	assified based on ava	ailable information.	
Resp	iratory sensitisation	I	
Not cl	assified based on ava	ailable information.	
	cell mutagenicity assified based on ava	ailable information.	
	nogenicity assified based on ava	ailable information.	
-	oductive toxicity assified based on ava	ailable information.	
	- single exposure assified based on ava	ailable information.	
STOT	- repeated exposur	e	
Not cl	assified based on ava	ailable information.	
Repe	ated dose toxicity		
Com	oonents:		
Bezlo	otoxumab:		
Speci		: Mouse	
NOAE		: 50 mg/kg	
	cation Route sure time	: Intravenous : 15 d	
Rema			adverse effects were reported
Speci	es	: Mouse	
NOAE		: 125 mg/kg	
	cation Route	: Intravenous	
Expos Rema	sure time	: 21 d	advorce offects were reported
кета	uks	. No significant a	adverse effects were reported



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-	ration toxicity lassified based on avail	able inf	ormation.	
Expe	erience with human ex	posure		
Com	ponents:			
Bezlo	otoxumab:			
Inhala	ation	: S	ymptoms: Na	ausea, Headache, Diarrhoea, Fever
SECTION	N 12: Ecological info	rmatio	n	
12.1 Toxi	city			
	ata available			
	<b>istence and degradab</b> i ata available	ility		
	ccumulative potential ata available			
	<b>ility in soil</b> ata available			
12.5 Resu	ults of PBT and vPvB a	assessr	nent	
Prod	uct:			
Asse	ssment	to Ve	be either pe	e/mixture contains no components considered rsistent, bioaccumulative and toxic (PBT), or t and very bioaccumulative (vPvB) at levels of r.
12.6 Othe	er adverse effects			
Prod	uct:			
Endo tial	crine disrupting poten-	er R (E	ed to have e	e/mixture does not contain components consid- ndocrine disrupting properties according to 57(f) or Commission Delegated regulation 00 or Commission Regulation (EU) 2018/605 at or higher.
SECTION	N 13: Disposal consi	deratio	ons	
13.1 Wast	te treatment methods			
Produ		A aı W di	ccording to the re not product aste codes s scussion with	accordance with local regulations. The European Waste Catalogue, Waste Codes at specific, but application specific. Should be assigned by the user, preferably in the waste disposal authorities. The of waste into sewer.

### SAFETY DATA SHEET



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SECTIO	N 14: Transport info	mation		
0201101				
14.1 UN r	number			
ADN		: Not regulated as a dangerous good		
ADR		: Not regulated as a dangerous good		
RID		: Not regulated as a dangerous good		
IMDO	3	: Not regulated as a dangerous good		
ΙΑΤΑ	L Contraction of the second seco	: Not regulated as a dangerous good		
14.2 UN p	proper shipping name			
ADN		: Not regulated as a dangerous good		
ADR		: Not regulated as a dangerous good		
RID		: Not regulated as a dangerous good		
IMDO	3	: Not regulated as a dangerous good		
ΙΑΤΑ	L Contraction of the second seco	: Not regulated as a dangerous good		
14.3 Tran	sport hazard class(es			
ADN		: Not regulated as a dangerous good		
ADR		: Not regulated as a dangerous good		
RID		: Not regulated as a dangerous good		
IMDO	3	: Not regulated as a dangerous good		
ΙΑΤΑ	L Contraction of the second seco	: Not regulated as a dangerous good		
14.4 Pack	king group			
ADN		: Not regulated as a dangerous good		
ADR		: Not regulated as a dangerous good		
RID		: Not regulated as a dangerous good		
IMDO	3	: Not regulated as a dangerous good		
ΙΑΤΑ	(Cargo)	: Not regulated as a dangerous good		
ΙΑΤΑ	(Passenger)	: Not regulated as a dangerous good		
14.5 Envi	ronmental hazards			
	egulated as a dangerou	-		
14.6 Special precautions for user Not applicable				
1/ 7 Tran	sport in bulk accordi	to Annex II of Marnol and the IBC Code		

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

Remarks : 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

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

#### 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 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 -



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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

#### Further information

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