



Vers 2.3	sion	Revision Date: 28.09.2024		S Number: 9031-00020		sue: 30.09.2023 sue: 22.07.2016
Sect	tion 1: I	dentification				
	Produc	t name	:	Bezlotoxumab Fo	ormulation	
	Manufa	acturer or supplier's o	deta	ils		
	Compa	ny	:	MSD		
	Addres	S	:	33 Whakatiki Stro Upper Hutt - Nev		g 908
	Teleph	one	:	0800 800 543		
	Emerge	ency telephone numbe	r:	0800 764 766 (0 CHEMCALL)	800 POISON)	0800 243 622 (0800
	E-mail	address	:	EHSDATASTEW	/ARD@msd.cor	n
	Recom	mended use of the c	hem	ical and restriction	ons on use	
		mended use tions on use	:	Pharmaceutical Not applicable		

### Section 2: Hazard 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	>= 1 -< 10

### Section 4: First-aid measures

If inhaled

: If inhaled, remove to fresh air. Get medical attention if symptoms occur.



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In	case	of skin contact	:		and soap as a precaution. tion if symptoms occur.			
In	case	of eye contact	:		rater as a precaution. tion if irritation develops and persists.			
lf	If swallowed		:	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.				
ar		portant symptoms ects, both acute and	:	None known.				
Pi	rotecti	on of first-aiders o physician	:		utions are necessary for first aid responders. cally and supportively.			
Sectio	on 5: F	ire-fighting measure	S					
Sı	uitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical				
	nsuita iedia	ble extinguishing	:	None known.				
	pecific ghting	hazards during fire-	:	Exposure to comb	pustion products may be a hazard to health.			
	azardo cts	ous combustion prod-	:	Carbon oxides				
Sp	•	extinguishing meth-	:	cumstances and t Use water spray t Remove undamag	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			
				so. Evacuate area.				
		protective equipment ghters	:	essary.	ed breathing apparatus for firefighting if nec- tective equipment.			
Sectio	on 6: A	Accidental release me	easi	ures				
tiv	/e equ	al precautions, protec- ipment and emer- procedures	:		ing advice (see section 7) and personal pro- recommendations (see section 8).			
Er	nviron	mental precautions	:	Prevent spreading barriers). Retain and dispos	he environment. akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages			



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			cannot be contain	ed.
	ods and materials for ainment and cleaning up	:	For large spills, pu ment to keep mat be pumped, store Clean up remainin bent. Local or national up posal of this mate employed in the of mine which regula Sections 13 and 1	t absorbent material. rovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container ng materials from spill with suitable absor- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements.
Section 7	: Handling and storage	!		
Tech	nical measures	:		measures under EXPOSURE SONAL PROTECTION section.
	I/Total ventilation ce on safe handling	:	Use only with ade Handle in accorda practice, based on sessment Take care to prev	
Hygie	ene measures	:	flushing systems a place. When using do no Wash contaminat The effective ope engineering contr appropriate degov industrial hygiene	emical is likely during typical use, provide ey and safety showers close to the working of eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, whing and decontamination procedures, monitoring, medical surveillance and the
Conc	litions for safe storage	:		abelled containers. ce with the particular national regulations.
Mate	rials to avoid	:		the following product types:

## Section 8: Exposure controls/personal protection

## Components 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



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	Engine	eering measures	:	technologies to co less quick connect All engineering co design and operat protect products,	engineering controls and manufacturing ontrol airborne concentrations (e.g., drip- tions). Introls should be implemented by facility ted in accordance with GMP principles to workers, and the environment. ions do not require special containment.
	Persor	nal protective equipme	ent		
	Filte Hand p	atory protection er type protection	:	sure assessment ommended guide Particulates type	exhaust ventilation is not available or expo- demonstrates exposures outside the rec- lines, use respiratory protection.
	Mat	erial	:	Chemical-resistar	it gloves
		otection nd body protection	:	If the work enviror mists or aerosols, Wear a faceshield	tes with side shields or goggles. Inment or activity involves dusty conditions, wear the appropriate goggles. If or other full face protection if there is a the contact to the face with dusts, mists, or
			· •		
Seci	tion 9: I	Physical and chemica	ı pr	operties	
	Appear	ance	:	Aqueous solution	1
	Colour		:	Colorless to pale	yellow
	Odour		:	No data available	)
	Odour <sup>-</sup>	Threshold	:	No data available	)
	pН		:	5.7 - 6.3	
	Melting	point/freezing point	:	No data available	)
	Initial b range	oiling point and boiling	:	No data available	
	Flash p	point	:	No data available	)
	Evapor	ation rate	:	No data available	9
	Flamm	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	)
		explosion limit / Upper ability limit	:	No data available	3



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		explosion limit / Lower bility limit	:	No data available	)
V	√apour	pressure	:	No data available	)
F	Relative	e vapour density	:	No data available	)
F	Relative	e density	:	No data available	9
C	Density		:	1.0146 g/cm <sup>3</sup>	
S	Solubili Wate	ty(ies) er solubility	:	No data available	9
		n coefficient: n-	:	Not applicable	
	octanol, Auto-igi	water nition temperature	:	No data available	
C	Decom	position temperature	:	No data available	)
٧	/iscosit Visc	ty osity, dynamic	:	1.2 mPa.s ( 25 °C	C)
	Visc	osity, kinematic	:	1.833 mm2/s ( 4	°C)
				1.183 mm2/s ( 25	5 °C)
E	Explosi	ve properties	:	Not explosive	
C	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.
Ν	Molecu	lar weight	:	No data available	)
	Particle Particle	characteristics 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

Exposure ro	outes
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: Inhalation



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Ingestion Eye contact

## Acute toxicity

Not classified based on available information.

#### **Components:**

### Bezlotoxumab:

Acute toxicity (other routes of<br/>administration)LD50 (Mouse): > 125 mg/kg<br/>Application Route: Intraveno

LD50 (Mouse): > 125 mg/kg 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



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Rem	arks	:	No significant a	adverse effects were reported
		-	-	
Spec NOA		:	Mouse 125 mg/kg	
	cation Route	÷	Intravenous	
	sure time	:	21 d	
Rem	arks	:	No significant a	adverse effects were reported
Aspi	ration toxicity			
Not c	lassified based on ava	ailable	information.	
Expe	erience with human e	xposı	ıre	
<u>Com</u>	ponents:			
Bezl	otoxumab:			
Inhal	ation	:	Symptoms: Na	usea, Headache, Diarrhoea, Fever
	ation 2: Ecological information	: ation	Symptoms: Na	usea, Headache, Diarrhoea, Fever
ction 1		: ation	Symptoms: Na	usea, Headache, Diarrhoea, Fever
ection 1 Ecot	2: Ecological information	: ation	Symptoms: Na	usea, Headache, Diarrhoea, Fever
ction 1 Ecot No da	2: Ecological informa oxicity ata available		Symptoms: Na	usea, Headache, Diarrhoea, Fever
ction 1 Ecot No da Pers	2: Ecological informa oxicity ata available istence and degradal		Symptoms: Na	usea, Headache, Diarrhoea, Fever
ction 1 Ecot No da Pers No da	2: Ecological informa oxicity ata available istence and degradal ata available	bility	Symptoms: Na	usea, Headache, Diarrhoea, Fever
ction 1 Ecot No da Pers No da Bioa	2: Ecological informa oxicity ata available istence and degradal ata available ccumulative potentia	bility	Symptoms: Na	usea, Headache, Diarrhoea, Fever
Ection 1 Ecot No da Pers No da Bioa No da	2: Ecological informa oxicity ata available istence and degradal ata available ccumulative potentia ata available	bility	Symptoms: Na	usea, Headache, Diarrhoea, Fever
ction 1 Ecot No da Pers No da Bioa No da No da	2: Ecological informa oxicity ata available istence and degradal ata available ccumulative potentia ata available ility in soil	bility	Symptoms: Na	usea, Headache, Diarrhoea, Fever
Ection 1 Ecot No da Pers No da Bioa No da No da	2: Ecological informa oxicity ata available istence and degradal ata available ccumulative potentia ata available	bility	Symptoms: Na	usea, Headache, Diarrhoea, Fever
Ection 1 Ecot No da Pers No da Bioa No da No da	2: Ecological informa oxicity ata available istence and degradal ata available ccumulative potentia ata available ility in soil	bility	Symptoms: Na	usea, Headache, Diarrhoea, Fever

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

## Section 14: Transport information

## International Regulations

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable



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Suba	idiony rick		Not applicable	
	idiary risk ing group	:	Not applicable Not applicable	
Labe		:	Not applicable	
	onmentally hazardous	÷	no	
ΙΔΤΔ	-DGR			
	D No.	:	Not applicable	
Prop	er shipping name	:	Not applicable	
Class		:	Not applicable	
	idiary risk	:	Not applicable	
	ing group	:	Not applicable	
Labe		:	Not applicable	
aircra	,	:	Not applicable	
	ing instruction (passen- ircraft)	:	Not applicable	
IMDO	G-Code			
	umber	:	Not applicable	
Prope	er shipping name	:	Not applicable	
Class		:	Not applicable	
	idiary risk	:	Not applicable	
	ing group		Not applicable	
Labe			Not applicable	
	Code		Not applicable	
Marin	ne pollutant		Not applicable	
	•	-		POL 73/78 and the IBC Code
Not a	pplicable for product as	sup	plied.	
Natio	onal Regulations			
NZS	5433			
UN ı	number	:	Not applicable	
	per shipping name	:	Not applicable	
Clas		:	Not applicable	
	sidiary risk	:	Not applicable	
	king group	:	Not applicable	
Labe		:	Not applicable	
Haz	chem Code	:	Not applicable	
Spec	ial precautions for use	r		

Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mix-ture

### **HSNO Approval Number**

Not applicable Tolerable Exposure Limits (TEL) Not applicable



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Environmental Exposure Limits (EEL)

Not applicable

### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

#### Section 16: Other information

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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 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 Substanc-



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es; (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

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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