

Golimumab Formulation

Version 2.15	Revision Date: 28.09.2024		DS Number: 3452-00027	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014
SECTION	1: Identification of	f the	substance/m	ixture and of the company/undertaking
1.1 Produ	ct identifier			
Trade	e name	:	Golimumab Fo	ormulation
1.2 Releva	ant identified uses of	the s	substance or m	ixture and uses advised against
Use o	of the Sub- e/Mixture	:	Pharmaceutic	_
Recor on us	mmended restrictions e	:	Not applicable	
1.3 Details	s of the supplier of th	e sa	fety data sheet	
Comp	••	:	MSD 117 16th Road	
Telep	hone	:	+27 11 655 30	000
	il address of person onsible for the SDS	:	EHSDATAST	EWARD@msd.com
-	gency telephone num 08-423-6000	ber		
SECTION	V 2: Hazards identifi	icati	on	
2.1 Classi	fication of the substa	ance	or mixture	
	sification (REGULATION iratory sensitisation, Ca	-	ory 1 H3	08) 34: May cause allergy or asthma symptoms or athing difficulties if inhaled.
2.2 Label	elements			
Label	lling (REGULATION (I	EC) I	No 1272/2008)	
Hazaı	rd pictograms	:		
0.	al word		Danger	

Precautionary statements	:	Response:	
		P304 + P340	IF INHALED: Remove person to fresh air and



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keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label: Golimumab

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Golimumab	476181-74-5	Resp. Sens. 1; H334	>= 10 - < 20

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
If inhaled	:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
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.



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			Rinse mouth t	horoughly with water.		
4.2 Most	important symptoms a	nd e	effects, both ac	ute and delayed		
Risks		: May cause allergy or asthma symptoms or breathing ties if inhaled.				
			other respirato	osure may aggravate preexisting asthma and bry disorders (e.g. emphysema, bronchitis, reac vsfunction syndrome).		
4.3 Indica	ation of any immediate	mec	lical attention	and special treatment needed		
Treat	tment	:	Treat sympton	natically and supportively.		
	N.F. Firefickting mee					
SECTIO	N 5: Firefighting meas	sur	es			
5.1 Exting	guishing media					
Suita	ble extinguishing media	:	Water spray Alcohol-resista Carbon dioxid Dry chemical			
Unsuitable extinguishing media		:	None known.			
5.2 Speci	al hazards arising from	the	substance or	mixture		
	ific hazards during fire-			ombustion products may be a hazard to health.		
Haza ucts	ardous combustion prod-	:	Carbon oxides Sulphur oxides			
5.3 Advic	e for firefighters					
Spec	cial protective equipment refighters	:		fire, wear self-contained breathing apparatus. protective equipment.		
Spec ods	ific extinguishing meth-	:	cumstances a Use water spra	ning measures that are appropriate to local cir- nd the surrounding environment. ay to cool unopened containers. maged containers from fire area if it is safe to d		

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment.
		Follow safe handling advice (see section 7) and personal pro-
		tective equipment recommendations (see section 8).



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6.2 Enviro	nmental precautions					
Enviro	onmental precautions	Prevent furth Prevent spre barriers). Retain and d Local author	 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. 			
6.3 Metho	ds and material for co	ontainment and cl	eaning up			
6.3 Methods and material for cor Methods for cleaning up		For large spi ment to keep be pumped, Clean up ren bent. Local or nation posal of this employed in mine which r Sections 13	inert absorbent material. Ils, provide dyking or other appropriate contain- omaterial from spreading. If dyked material can store recovered material in appropriate container. maining materials from spill with suitable absor- onal regulations may apply to releases and dis- material, as well as those materials and items the cleanup of releases. You will need to deter- egulations are applicable. and 15 of this SDS provide information regarding or national requirements.			

6.4 Reference to other sections

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

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 Advice on safe handling	::	Use only with adequate ventilation. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira- tory irritants or sensitisers. 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 contami- nated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage	:	Keep in properly labelled containers. Keep tightly closed.
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areas	and containers		Store in accorda	nce with the particular national regulations.
Advice on common storage		:	Do not store with Strong oxidizing Gases	the following product types: agents
-	f ic end use(s) ific 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
Golimumab	476181-74- 5	TWA	70 µg/m3 (OEB 3)	Internal

8.2 Exposure controls

Engineering measures

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Personal	protective	equipment	
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Eye/face protection	:	Wear the following personal protective equipment: Safety glasses
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	:	Skin should be washed after contact.
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	Aqueous solution
Colour	:	opalescent
Odour	:	No data available



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C	Odour ⊺	Fhreshold	:	No data available	
F	эΗ		:	5,5	
Ν	Melting	point/freezing point	:	No data available	
		oiling point and boiling	:	No data available	
	ange Flash p	oint	:	No data available	•
E	Evapora	ation rate	:	No data available	
F	-lamma	ability (solid, gas)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
١	/apour	pressure	:	No data available	
F	Relative	e vapour density	:	No data available	
F	Relative	e density	:	No data available	
F		er solubility n coefficient: n-	:	soluble No data available	
A	Auto-igi	nition temperature	:	No data available	
Γ	Decom	position temperature	:	No data available	
١	/iscosit Visc	ty osity, kinematic	:	No data available	
E	Explosi	ve properties	:	Not explosive	
C	Oxidizir	ng properties	:	The substance or	mixture is not classified as oxidizing.
9.2 O	ther in	formation			
F	Flamma	ability (liquids)	:	No data available	
Ν	Molecu	lar weight	:	No data available	
F	Particle	size	:	No data available	•

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.



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10.2 C	chemical stability		
	table under normal condition	IS.	
10.3 P	ossibility of hazardous rea	actions	
Н	azardous reactions	: Can react with	n strong oxidizing agents.
40.4.0	anditions to sweid		
	conditions to avoid onditions to avoid	: None known.	
Ŭ		. None known.	
10.5 lr	ncompatible materials		
N	laterials to avoid	: Oxidizing age	nts
40.01			
	lazardous decomposition p o hazardous decomposition		
	•		
SECI	ION 11: Toxicological in	iformation	
11.1 lr	nformation on toxicologica	Il effects	
	formation on likely routes of		
e	xposure	Skin contact	
		Ingestion Eye contact	
А	cute toxicity	·	
N	ot classified based on availa	ble information.	
S	kin corrosion/irritation		
N	ot classified based on availa	able information.	
S	erious eye damage/eye irri	itation	
N	ot classified based on availa	able information.	
R	espiratory or skin sensitis	ation	
S	kin sensitisation		
N	ot classified based on availa	ble information.	
R	espiratory sensitisation		
N	lay cause allergy or asthma	symptoms or breath	ning difficulties if inhaled.
<u>C</u>	omponents:		
G	olimumab:		
	xposure routes	: Inhalation	acitization by inholation
A	ssessment	: May cause ser	nsitisation by inhalation.
G	erm cell mutagenicity		
	ot classified based on availa	ble information.	
С	arcinogenicity		
	ot classified based on availa	ble information.	



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•	roductive toxicity classified based on avail	able information.	
<u>Con</u>	nponents:		
Goli	imumab:		
Effe	cts on fertility	Species: Mo Application I Fertility: NO Test Type: F Species: Mo Application I	Route: Intravenous injection AEL Parent: 40 mg/kg body weight Fertility/early embryonic development
Effects on foetal develop- : ment		Species: Mo Teratogenic Embryo-foet Test Type: E Species: Mo Developmer Test Type: E Species: Mo Application I Teratogenic Embryo-foet	ity: NOAEL: 100 mg/kg body weight tal toxicity: NOAEL: 100 mg/kg body weight Development onkey ntal Toxicity: NOAEL F1: 50 mg/kg body weight Embryo-foetal development

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Golimumab:

Species NOAEL Application Route Exposure time Number of exposures		Monkey 50 mg/kg Intravenous 6 Months Intermittent
Species NOAEL Application Route Exposure time	: : :	Monkey 25 mg/kg Subcutaneous 6 Months
Species	:	Mouse



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NOAE Applic	EL cation Route	:	40 mg/kg Intravenous	
-	ation toxicity			
	lassified based on ava			
Expe	rience with human e	xposu	ire	
Com	oonents:			
Golin	numab:			
Inhala	ation	:		ild infections, upper respiratory tract infection, , bronchitis, sinusitis, fungal infections
SECTION	12: Ecological inf	orma	tion	
12.1 Toxic	city			
<u>Com</u>	oonents:			
Golin	numab:			
Ecoto	oxicology Assessme	nt		
Acute	aquatic toxicity	:	No data availa	able
Chror	nic aquatic toxicity	:	No data availa	able
	stence and degrada	bility		
	ccumulative potentia	l		
12.4 Mobi No da	lity in soil ata available			
12.5 Resu	Its of PBT and vPvB	asses	ssment	
Produ	uct:			
	ssment	:	to be either pe	e/mixture contains no components considered ersistent, bioaccumulative and toxic (PBT), or t and very bioaccumulative (vPvB) at levels of r.
12.6 Othe	r adverse effects			
Produ	uct:			
Endoo tial	crine disrupting poten-	• :	ered to have e REACH Article	e/mixture does not contain components consid endocrine disrupting properties according to e 57(f) or Commission Delegated regulation 00 or Commission Regulation (EU) 2018/605 a



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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number

	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.	2 UN proper shipping name		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.	3 Transport hazard class(es)		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.	4 Packing group		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	IATA (Cargo)	:	Not regulated as a dangerous good
	IATA (Passenger)	:	Not regulated as a dangerous good



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	14.5 Environmental hazards Not regulated as a dangerous good					
	14.6 Special precautions for user Not applicable					
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code						
Rema	rks	: Not applicable for	or product as supplied.			
SECTION 15: Regulatory information						
15.1 Safety, health and environmental regulations/legislation specific for the substance or mix- ture						

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

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 H-Statements

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Full text of other abbreviations

Resp. Sens. : Respiratory sensitisation

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;



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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 -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 Sheet		eChem Portal search results and European Chemicals Agen-
Sheet		cy, http://echa.europa.eu/

Classification of the mixture:

Resp. Sens. 1 H334

Classification procedure: Calculation method

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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