

according to the Globally Harmonized System

## **Golimumab Formulation**

Version 3.0	Revision Date: 28.09.2024	SDS Number: 26436-00026		Date of last issue: 29.09.2023 Date of first issue: 29.10.2014	
1. PRODU	ICT AND COMPANY ID	DENT	IFICATION		
Product name		:	Golimumab Formulation		
Manı	facturer or supplier's	deta	ils		
Comp	bany	:	MSD		
Addre	Address		Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207		
Telep	Telephone		+1-908-740-4000		
Emer	Emergency telephone number		+1-908-423-6000		
E-ma	E-mail address		EHSDATASTEWARD@msd.com		
Reco	mmended use of the c	hem	ical and restrict	ions on use	
		:	Pharmaceutical Not applicable		

### 2. HAZARDS IDENTIFICATION

## Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification Respiratory sensitisation	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements	:	Prevention:
		<ul> <li>P233 Keep container tightly closed.</li> <li>P260 Do not breathe mist or vapours.</li> <li>P271 Use only outdoors or with adequate ventilation.</li> <li>P280 Wear protective gloves/ protective clothing.</li> <li>P284 Wear respiratory protection.</li> </ul>
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		keep comfort P342 + P316	IF INHALED: Remove person to fresh air and able for breathing. If experiencing respiratory symptoms: Get emer- al help immediately.
		<b>Storage:</b> P403 Store ir	n a well-ventilated place.
		<b>Disposal:</b> P501 Dispos	e of contents/ container to an approved waste

disposal plant.

#### Other hazards which do not result in classification

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture
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#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Golimumab	476181-74-5	>= 10 - < 20

### 4. 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.
If inhaled	:	
		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	:	
		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.
Most important symptoms and effects, both acute and	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
delayed		Excessive exposure may aggravate preexisting asthma and
		other respiratory disorders (e.g. emphysema, bronchitis, reac-
		tive airways dysfunction syndrome).
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).
Notes to physician	:	Treat symptomatically and supportively.

### **5. FIREFIGHTING MEASURES**



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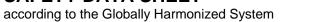
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	Suitable extinguishing media		:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical				
	Unsuitable extinguishing media		:	None known.				
	Specific hazards during fire- fighting		:	Exposure to comb	oustion products may be a hazard to health.			
	Hazardous combustion prod- ucts		:	Carbon oxides Sulphur oxides				
	Specific extinguishing meth- ods		:	Use extinguishing measures that are appropriate to local or cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe t so. Evacuate area.				
	Special for firefi	protective equipment ghters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus.			

## 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. 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.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment 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 absor- bent. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE





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Loca	nical measures I/Total ventilation ce on safe handling	CONTROLS Use only wit Do not breat Do not swall Avoid contat Avoid prolor Handle in ac practice, bas sessment Keep contai Already sen to asthma, a should cons tory irritants	ct with eyes. aged or repeated contact with skin. ccordance with good industrial hygiene and safety sed on the results of the workplace exposure as- ner tightly closed. sitised individuals, and those susceptible illergies, chronic or recurrent respiratory disease, ult their physician regarding working with respira- or sensitisers. prevent spills, waste and minimize release to the
Cond	litions for safe storage	Keep tightly	
Mate	rials to avoid		ordance with the particular national regulations. with the following product types: zing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components		CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis			
			exposure)	concentration				
Golimumab		476181-74-5	TWA	70 µg/m3 (OEB 3)	Internal			
Engineering measures :			Ensure adequate ventilation, especially in confined areas.					
		Minimize work	place exposure	concentrations.				
Personal protective equipn	nent	:						
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 Hand protection	:	Particulates type						
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.						
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Ski	in and body protection	:	Safety glasses Skin should be wa	ashed after contact.		
Hy	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.			
9. PHYS	SICAL AND CHEMICAL PI	ROF	PERTIES			
Ар	pearance	:	Aqueous solutior	1		
Co	lour	:	opalescent			
Od	our	:	No data available	9		
Od	our Threshold	:	No data available	9		
рH		:	5.5			
Me	Iting point/freezing point	:	No data available	9		
Init rar	ial boiling point and boiling Ige	:	: No data available			
Fla	sh point	:	No data available	9		
Eva	aporation rate	:	No data available	9		
Fla	mmability (solid, gas)	:	Not applicable			
Fla	mmability (liquids)	:	No data available	9		
	per explosion limit / Upper mmability limit	:	: No data available			
	wer explosion limit / Lower mmability limit	:	No data available	9		
Va	pour pressure	:	No data available	9		
Re	lative vapour density	:	No data available	9		
Re	lative density	:	No data available	9		
	lubility(ies) Water solubility	:	soluble			
	rtition coefficient: n- anol/water	:	No data available	9		
	anoi/water to-ignition temperature	:	No data available	9		
De	composition temperature	:	No data available	9		



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Visco Vi	sity scosity, kinematic	: No da	ta available			
Explo	osive properties	: Not ex	kplosive			
Oxidi	zing properties	: The s	ubstance of	mixture is not classified as oxidizing.		
Mole	cular weight	: No da	ta available			
	cle characteristics cle size	: No data available				
10. STAB		/				
Chen Possi tions Cond Incon Haza	Reactivity Chemical stability Possibility of hazardous reac- tions Conditions to avoid Incompatible materials Hazardous decomposition products		<ul> <li>Not classified as a reactivity hazard.</li> <li>Stable under normal conditions.</li> <li>Can react with strong oxidizing agents.</li> <li>None known.</li> <li>Oxidizing agents</li> <li>No hazardous decomposition products are known.</li> </ul>			
11. TOXIC	COLOGICAL INFORMA	ΓΙΟΝ				
Inforr expos	nation on likely routes of sure	: Inhalat Skin co Ingesti Eye co	ontact on			
	<b>e toxicity</b> lassified based on availa	ble informa	tion.			
	corrosion/irritation lassified based on availa	ble informa	tion.			
-						

#### 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

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

### Components:

### Golimumab:

Exposure routes	:	Inhalation
Assessment	:	May cause sensitisation by inhalation.

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Not c Carci Not c Repr Not c	n cell mutagenicity lassified based on ava inogenicity lassified based on ava oductive toxicity lassified based on ava	ilable information.	
	ponents:		
Effec	numab: ts on fertility	Species: Me Application Fertility: NC Test Type: I Species: Me Application Fertility: NC	Route: Intravenous injection DAEL Parent: 40 mg/kg body weight Fertility/early embryonic development buse, female Route: Intravenous injection DAEL Parent: 40 mg/kg body weight
Effec ment	ts on foetal develop-	Species: Mo Teratogenic Embryo-foe Test Type: I Species: Mo Developme Test Type: I Species: Mo Application Teratogenic Embryo-foe	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	:	Monkey
NOAEL	:	50 mg/kg
Application Route	:	Intravenous
Exposure time	:	6 Months
Number of exposures	:	Intermittent

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		:	Monkey 25 mg/kg Subcutaneous 6 Months	
Spec NOAI Applie		:	Mouse 40 mg/kg Intravenous	
-	r <b>ation toxicity</b> lassified based on availa	ıble iı	nformation.	
Expe	rience with human exp	osur	е	
Com	ponents:			
Golin	numab:			
Inhala	ation			nfections, upper respiratory tract infection, on
12. ECOL	OGICAL INFORMATIO			, , , ,
		-		
Ecoto	oxicity			
Com	ponents:			
Golin	numab:			
	oxicology Assessment e aquatic toxicity		No data available	
Chror	nic aquatic toxicity	:	No data available	
	<b>stence and degradabil</b> ata available	ity		
	ccumulative potential ata available			
	<b>lity in soil</b> ata available			
	r adverse effects ata available			
13. DISPO	SAL CONSIDERATION	IS		
-	osal methods		Do not dianago of	

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.



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#### **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 IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

### 15. REGULATORY INFORMATION

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

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

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

#### **16. OTHER INFORMATION**

Revision Date	:	28.09.2024
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/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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

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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

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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