according to GB/T 16483 and GB/T 17519



# **Golimumab Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
2.0	2024/09/28	26428-00027	Date of first issue: 2014/10/29

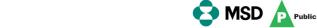
## **1. PRODUCT AND COMPANY IDENTIFICATION**

Product name	:	Golimumab Formulation						
Manufacturer or supplier's de	Manufacturer or supplier's details							
Company	:	MSD						
Address	:	199 Wenhai North Road HEDA, Hangzhou - Zhejiang Province - CHINA 310018						
Telephone	:	908-740-4000						
Emergency telephone number	:	86-571-87268110						
E-mail address	:	EHSDATASTEWARD@msd.com						
Recommended use of the chemical and restrictions on use								
Recommended use Restrictions on use	:	Pharmaceutical Not applicable						

### 2. HAZARDS IDENTIFICATION

## **Emergency Overview**

Appearance Colour Odour	:	Aqueous solution opalescent No data available
May cause allergy or asthma	sym	ptoms or breathing difficulties if inhaled.
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	:	<b>Prevention:</b> P261 Avoid breathing mist or vapours.



according to GB/T 16483 and GB/T 17519

# **Golimumab Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
2.0	2024/09/28	26428-00027	Date of first issue: 2014/10/29

P284 Wear respiratory protection.

#### **Response:**

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

## Physical and chemical hazards

Not classified based on available information.

#### Health hazards

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

#### **Environmental hazards**

Not classified based on available information.

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

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### 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 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. 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.

according to GB/T 16483 and GB/T 17519



# **Golimumab Formulation**

Version 2.0	Revision Date: 2024/09/28		DS Number: 428-00027	Date of last issue: 2024/04/06 Date of first issue: 2014/10/29		
del	delayed		Excessive exposure may aggravate preexisting asthma other respiratory disorders (e.g. emphysema, bronchitis,			
Protection of first-aiders		:	tive airways dysfunction syndrome). 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).			
No	tes to physician	:		cally and supportively.		
5. FIRE	FIGHTING MEASURES					
Su	itable extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical			
	suitable extinguishing dia	:	None known.			
	ecific hazards during fire- nting	:	Exposure to comb	pustion products may be a hazard to health.		
	Hazardous combustion prod- ucts		Carbon oxides Sulphur oxides			
Sp od:	ecific extinguishing meth- S	:	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 protective equipment for firefighters			e, wear self-contained breathing apparatus. rective equipment.		
6. ACC	DENTAL RELEASE MEA	SUF	RES			

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-

according to GB/T 16483 and GB/T 17519



# **Golimumab Formulation**

Version 2.0	Revision Date: 2024/09/28	SDS Number: 26428-00027	Date of last issue: 2024/04/06 Date of first issue: 2014/10/29
		be pumped, s Clean up rem bent. Local or natio posal of this n employed in t mine which re Sections 13 a	material from spreading. If dyked material can tore recovered material in appropriate container. aining materials from spill with suitable absor- nal regulations may apply to releases and dis- naterial, as well as those materials and items he cleanup of releases. You will need to deter- egulations are applicable. nd 15 of this SDS provide information regarding or national requirements.
7. HANDL	ING AND STORAGE		
Hand	ling		
	nical measures		ing measures under EXPOSURE PERSONAL PROTECTION section.
Advic	Total ventilation e on safe handling ance of contact	<ul> <li>Use only with</li> <li>Do not breath</li> <li>Do not swallo</li> <li>Avoid contact</li> <li>Avoid prolong</li> <li>Handle in acc</li> <li>practice, base</li> <li>sessment</li> <li>Keep containe</li> <li>Already sensi</li> <li>to asthma, alle</li> <li>should consult</li> <li>tory irritants o</li> </ul>	adequate ventilation. e mist or vapours. w. with eyes. jed or repeated contact with skin. ordance with good industrial hygiene and safety ed on the results of the workplace exposure as- er tightly closed. tised individuals, and those susceptible ergies, chronic or recurrent respiratory disease, it their physician regarding working with respira- r sensitisers. prevent spills, waste and minimize release to the
	<b>ge</b> itions for safe storage ials to avoid	Keep tightly c Store in accor : Do not store v	rdance with the particular national regulations. with the following product types:
<b>.</b> .	aina motorial	Strong oxidizi	ng agents

## Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Golimumab	476181-74-5	TWA	70 µg/m3 (OEB 3)	Internal

according to GB/T 16483 and GB/T 17519



# **Golimumab Formulation**

Version 2.0	Revision Date: 2024/09/28		9S Number: 428-00027	Date of last issue: 2024/04/06 Date of first issue: 2014/10/29		
Engi	neering measures	:		ventilation, especially in confined areas. ce exposure concentrations.		
Pers	onal protective equip	ment				
	Respiratory protection		If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.			
	Iter type	:	Particulates type			
Eye/f	Eye/face protection		Wear the following personal protective equipment:			
	Skin and body protection Hand protection		Safety glasses Skin should be washed after contact.			
М	aterial	:	Chemical-resista	nt gloves		
R	Remarks		Choose gloves to protect hands against chemicals depend on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is determined for the product. Change gloves often! For spec 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.			
Hygie	ene measures	:	If exposure to che eye flushing syste ing place. When using do no	emical is likely during typical use, provide ems and safety showers close to the work- ot eat, drink or smoke. ed clothing before re-use.		

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Colour	:	opalescent
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	5.5
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

according to GB/T 16483 and GB/T 17519



# **Golimumab Formulation**

ersion 0	Revision Date: 2024/09/28		S Number: 28-00027	Date of last issue: 2024/04/06 Date of first issue: 2014/10/29
Flam	mability (solid, gas)	:	Not applicable	
Flam	mability (liquids)	:	No data available	9
	r explosion limit / Upper nability limit	:	No data available	3
	r explosion limit / Lower nability limit	:	No data available	9
Vapo	ur pressure	:	No data available	)
Relat	ive vapour density	:	No data available	)
Relat	ive density	:	No data available	)
	bility(ies) ater solubility	:	soluble	
	ion coefficient: n- ol/water	:	No data available	)
	ignition temperature	:	No data available	)
Deco	mposition temperature	:	No data available	)
Visco Vi	sity scosity, kinematic	:	No data available	)
Explo	osive properties	:	Not explosive	
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.
Moleo	cular weight	:	No data available	)
	cle characteristics cle size	:	No data available	9

## **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	:	No hazardous decomposition products are known.
products		



according to GB/T 16483 and GB/T 17519

# **Golimumab Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
2.0	2024/09/28	26428-00027	Date of first issue: 2014/10/29

## **11. TOXICOLOGICAL INFORMATION**

Exposure routes

: Inhalation Skin contact Ingestion Eye contact

#### Acute toxicity

Not classified based on available information.

#### 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**

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

### Components:

#### Golimumab:

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

#### Germ cell mutagenicity

Not classified based on available information.

#### Carcinogenicity

Not classified based on available information.

#### **Reproductive toxicity**

Not classified based on available information.

#### **Components:**

### Golimumab:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Mouse, male Application Route: Intravenous injection Fertility: NOAEL Parent: 40 mg/kg body weight
		Test Type: Fertility/early embryonic development Species: Mouse, female Application Route: Intravenous injection Fertility: NOAEL Parent: 40 mg/kg body weight
Effects on foetal develop-	:	Test Type: Embryo-foetal development

according to GB/T 16483 and GB/T 17519



# **Golimumab Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
2.0	2024/09/28	26428-00027	Date of first issue: 2014/10/29
ment		Embryo-foetal to Test Type: Deve Species: Monkey Developmental T Test Type: Embr Species: Mouse Application Route Teratogenicity: N Embryo-foetal to	IOAEL: 100 mg/kg body weight xicity: NOAEL: 100 mg/kg body weight lopment

#### 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

Species	: Monkey
NOAEL	: 25 mg/kg
Application Route	: Subcutaneous
Species NOAEL Application Route Exposure time	: 6 Months

Species	: Mouse
NOAEL	: 40 mg/kg
Application Route	: Intravenous

#### Aspiration toxicity

Not classified based on available information.

#### Experience with human exposure

#### **Components:**

#### Golimumab:

- Inhalation

: Symptoms: mild infections, upper respiratory tract infection, viral infections, bronchitis, sinusitis, fungal infections



according to GB/T 16483 and GB/T 17519

# **Golimumab Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
2.0	2024/09/28	26428-00027	Date of first issue: 2014/10/29

## **12. ECOLOGICAL INFORMATION**

Ecotoxicity	
Components:	
Golimumab:	
Ecotoxicology Assessment	
Acute aquatic toxicity :	No data available
Chronic aquatic toxicity :	No data available
Persistence and degradability	
No data available	
Bioaccumulative potential	
No data available	
Mobility in soil	
No data available	
Other adverse effects	
No data available	
13. DISPOSAL CONSIDERATIONS	
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.

## 14. TRANSPORT INFORMATION

## International Regulations

UNRTDG		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no
IATA-DGR		
UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable

according to GB/T 16483 and GB/T 17519



# **Golimumab Formulation**

Version 2.0	Revision Date: 2024/09/28		DS Number: 6428-00027	Date of last issue: 2024/04/06 Date of first issue: 2014/10/29
Pack Labe Pack aircra Pack	idiary risk ing group Is ing instruction (cargo aft)	:	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
IMDO	G-Code		Not applicable	

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	no

## Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### National Regulations

#### GB 6944/12268

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Marine pollutant	:	no

## Special precautions for user

Not applicable

#### **15. REGULATORY INFORMATION**

National regulatory information Law on the Prevention and Control of Occupational Diseases				
Regulations on Safety Management of Hazardous Chemicals				
Catalogue of Hazardous Chemicals	This product is not listed in the cata- logue of hazardous chemicals and it does not meet the definition of haz- ardous chemicals and its principles of determination.			
Identification of Major Hazard Installations for Hazardous 18218)	Chemicals (GB : Not listed			
Hazardous Chemicals for Priority Management under	: Not listed			



according to GB/T 16483 and GB/T 17519

# **Golimumab Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
2.0	2024/09/28	26428-00027	Date of first issue: 2014/10/29

# SAWS

Regulations on Labour Prote Catalogue of Highly Toxic Cher	<b>ction in Workplaces wh</b> nicals	nere :	• Toxic Substances are Used Not listed	
Regulation of Environmental and Export of Toxic Chemica	-	rst	Import of Chemicals and the Import	
China Severely Restricted Toxi and Export	c Chemicals for Import	:	Not listed	
Regulation on the Administra	tion of Precursor Cher	nica	als	
Catalogue and Classification of Precursor Chemicals : Not listed				
Yangtze River Protection Law				
This product does not contain any dangerous chemicals prohibited for inland river transport.				
The components of this prod AICS	uct are reported in the : not determined	foll	owing inventories:	
DSL	: not determined			
IECSC	: not determined			

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

Revision Date	:	2024/09/28
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 Agency, 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

: yyyy/mm/dd

#### 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

according to GB/T 16483 and GB/T 17519



# **Golimumab Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
2.0	2024/09/28	26428-00027	Date of first issue: 2014/10/29

- 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

### Disclaimer

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.

CN / EN