

Golimumab Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.16	28.09.2024	26444-00028	Date of first issue: 29.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier		
	Trade name	:	Golimumab Formulation
1.2	Relevant identified uses of th	ne s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD
			Kilsheelan
			Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@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)

Respiratory sensitisation, Category 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2 Label elements

Signal word

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



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Hazard statements	:	H334	May cause allergy or asthma symptoms or breathing
		difficult	ties if inhaled.



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Preca	utionary statements	keep comfortab	IF INHALED: Remove person to fresh air and ble for breathing. If experiencing respiratory symptoms: Call a FER/ 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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 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.	Classification	Concentration (% w/w)
Golimumab	Registration number 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).



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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		:		and soap as a precaution. ation if symptoms occur.
In	case of eye contact	:		vater as a precaution. ntion if irritation develops and persists.
lf s	If swallowed		Get medical atter	NOT induce vomiting. htion if symptoms occur. oughly with water.
4 2 Mos	st important symptoms a	nd	effects both acute	e and delayed
Ris		:		y or asthma symptoms or breathing difficul-
			other respiratory	ure may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, reac- unction syndrome).
				1
	eatment	me :		d special treatment needed ically and supportively.
SECTI	ON 5: Firefighting mea	sur	es	
51 Exti	inguishing media			
	itable extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide ((Dry chemical	
	suitable extinguishing edia	:	None known.	
5.2 Spe	cial hazards arising from	h the	e substance or mi	xture
Sp	-	:		bustion products may be a hazard to health.
Ha uct	zardous combustion prod- s	:	Carbon oxides Sulphur oxides	
5.3 Adv	vice for firefighters			
Sp	ecial protective equipment firefighters	:		e, wear self-contained breathing apparatus. tective equipment.



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Specific extinguishing meth- ods		 Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. 				
SECTION	N 6: Accidental relea	se measures				
6.1 Perso	nal precautions, prote	ctive equipment a	and emergency procedures			
Perso	onal precautions	•	l protective equipment. nandling advice (see section 7) and personal pro-			

6.2 Environmental precautions

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.
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tective equipment recommendations (see section 8).

6.3 Methods and material for containment and cleaning up

Methods for 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.

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	: Use only with adequate ventilation.
Advice on safe handling	: Do not breathe mist or vapours.
_	Do not swallow.

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according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Hygiene measures		:	 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 assessment 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 respiratory irritants or sensitisers. Take care to prevent spills, waste and minimize release to the environment. 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. 				
7.2 (Conditi	ons for safe storage,	inc	luding any incom	patibilities		
	•	ements for storage and containers	:		abelled containers. Keep tightly closed. ace with the particular national regulations.		
	Stro		Do not store with Strong oxidizing a Gases	the following product types: agents			
7.3 S	Specifi	c end use(s)					
	Specifi	c 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							
Eye/face protection	:	Wear the following personal protective equipment: Safety glasses Equipment should conform to NS EN 166					
Hand protection							
Material	:	Chemical-resistant gloves					



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Re	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				
	and body protection ratory protection	: If adequate I sure assessi ommended g	be washed after contact. bocal exhaust ventilation is not available or expo- nent demonstrates exposures outside the rec- guidelines, use respiratory protection.				
Filt	ter type	: Particulates	hould conform to NS EN 143 type (P)				

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	Aqueous solution
Colour	:	opalescent
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	5,5

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according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		ity, kinematic	:	No data available	9
S	olubility(Water	ies) solubility	:	soluble	
	Partition o	coefficient: n- ater	:	No data available	2
V	Vapour pressure		:	No data available	9
R	Relative density		:	No data available	9
R	Relative vapour density		:	No data available	9
Р	article cl Particl	haracteristics e size	:	No data available	
	her info				
E	xplosive	S	:	Not explosive	
O	Oxidizing	properties	:	The substance o	r mixture is not classified as oxidizing.
E	ivaporati	on rate	:	No data available	9
N	lolecular	weight	:	No data available	2

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

0.3 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.



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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of	:	Inhalation
exposure		Skin conta
		Ingestion

act 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



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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	:	Monkey
NOAEL		50 mg/kg
Application Route	:	Intravenous
Exposure time	:	6 Months
Number of exposures	:	Intermittent
Snacias		Monkey

Species	: Monkey	
NOAEL	: 25 mg/kg	
Application Route	: Subcutaneou	JS
Exposure time	: 6 Months	
-		
Creation	. Mouse	

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

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

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according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		levels of 0.1%	or higher.
Expe	rience with human exp	osure	
Com	ponents:		
Golir Inhala	numab: ation		ild infections, upper respiratory tract infection, s, bronchitis, sinusitis, fungal infections
SECTION	N 12: Ecological infor	mation	
12.1 Toxi	city		
Com	ponents:		
Golir	numab:		
	oxicology Assessment e aquatic toxicity	: No data availa	able
Chro	nic aquatic toxicity	: No data availa	able
	istence and degradabil ata available	ity	
	ccumulative potential ata available		
	i lity in soil ata available		
12.5 Resu	Ilts of PBT and vPvB as	ssessment	
<u>Prod</u> Asse	<u>uct:</u> ssment	to be either pe	e/mixture contains no components considered ersistent, bioaccumulative and toxic (PBT), or at and very bioaccumulative (vPvB) at levels of or.
12.6 Endo	ocrine disrupting prope	rties	
Prod	uct:		
Asse	ssment	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 at o or higher.
12.7 Othe	r adverse effects		
No da	ata available		



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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 or ID 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



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IMDG		: Not regulated	as a dangerous good	
ΙΑΤΑ	(Cargo)	: Not regulated as a dangerous good		
ΙΑΤΑ	(Passenger)	: Not regulated as a dangerous good		
14.5 Envir	onmental hazards			
Not re	gulated as a dangerou	is good		
-	ial precautions for us	er		
14 7 Mariti	ime transport in bulk	according to IMO	instruments	

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3
		Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parlian	nent	and of the Council on the control of

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.



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The c AICS	• •	roduct are reporte : not determin	d in the following inventories: ed
DSL		: not determin	ed
IECS	с	: not determin	ed
15 2 Chan	nical cafaty accord	ant	

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: 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 - Interna-tional 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 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/
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Classification of the mixture:

Classification procedure: Calculation method

Resp. Sens. 1

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.

NO / EN