

Golimumab Formulation

Versi 7.2		Revision Date: 28.09.2024		5 Number: 46-00026		sue: 29.09.2023 sue: 29.10.2014
0	an de Isla					
Secti	ion 1: Ia	entification				
F	Product	name	:	Golimumab Form	nulation	
r	Manufac	cturer or supplier's d	letai	ls		
(Compan	у	:	MSD		
ŀ	Address		:	33 Whakatiki Stre Upper Hutt - New		g 908
٦	Telephor	ne	:	0800 800 543		
E	Emerger	ncy telephone number	• :	0800 764 766 (08 CHEMCALL)	800 POISON)	0800 243 622 (0800
E	E-mail a	ddress	:	EHSDATASTEW	ARD@msd.cor	n
F	Recomn	nended use of the cl	nemi	ical and restrictic	ons on use	
		nended use	:	Pharmaceutical		
F	Restrictio	ons on use	:	Not applicable		
Secti	ion 2: Ha	azard identification				
(GHS Cla	assification				
F	Respirat	ory sensitisation	:	Category 1		
(GHS lab	el elements				
ł	Hazard pictograms		:			
S	Signal word		:	Danger		

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

Precautionary statements : Prevention:

Hazard statements

P261 Avoid breathing mist or vapours. 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.



Golimumab Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.09.2023
7.2	28.09.2024	26446-00026	Date of first issue: 29.10.2014

Disposal:

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

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)
Golimumab	476181-74-5	>= 10 -< 20

Section 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
If inhaled	:	advice. 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	:	
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 delayed	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled. 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.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing	:	None known.



Golimumab Formulation

Version 7.2	Revision Date: 28.09.2024		0S Number: 446-00026	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014
me	dia			
	ecific hazards during fire- hting	:	Exposure to comb	oustion products may be a hazard to health.
Ha uct	zardous combustion prod-	:	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
	ecial protective equipment firefighters	:		e, wear self-contained breathing apparatus. tective equipment.
Sectior	n 6: Accidental release me	eas	ures	
tive	rsonal precautions, protec- e equipment and emer- ncy procedures	:	Follow safe handl	tective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
En	vironmental precautions	:	Prevent spreading barriers). Retain and dispos	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
	ethods and materials for ntainment and cleaning up	:	For large spills, pu ment to keep mat be pumped, store Clean up remainin bent. Local or national u posal of this mate employed in the c 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. 15 of this SDS provide information regarding tional requirements.

Section 7: Handling and storage

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.



Golimumab Formulation

Version 7.2	Revision Date: 28.09.2024	SDS Numbe 26446-0002	
Advid	Advice on safe handling		preathe mist or vapours. wallow. ontact with eyes. olonged or repeated contact with skin. n accordance with good industrial hygiene and safety based on the results of the workplace exposure as- nt ntainer tightly closed. sensitised individuals, and those susceptible ha, allergies, chronic or recurrent respiratory disease, consult their physician regarding working with respira- tants or sensitisers. re to prevent spills, waste and minimize release to the
Hygi	Hygiene measures		nent. ure to chemical is likely during typical use, provide eye systems and safety showers close to the working sing do not eat, drink or smoke.
	Conditions for safe storage Materials to avoid		ontaminated clothing before re-use. properly labelled containers. htly closed. accordance with the particular national regulations. tore with the following product types: oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

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				
Engineering measures :			Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.						
Personal protective equip	oment								
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 ty		-F					
Material :		Chemical-resistant gloves							
Remarks	on the concern stance and sp determined fo	tration and quar ecific to place o r the product. Cl	ds against chemicals ntity of the hazardous f work. Breakthrough nange gloves often! F clarifying the resistand	sub- time is not or special					



Golimumab Formulation

Version 7.2	Revision Date: 28.09.2024		S Number: 146-00026	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014
	rotection and body protection	:	glove manufac end of workda Wear the follo Safety glasses	wing personal protective equipment:
Section 9:	Physical and chemica	l pr	operties	
Appea	arance	:	Aqueous solu	ution
Colou	r	:	opalescent	
Odour	r	:	No data avail	able
Odour	r Threshold	:	No data avail	able
рН		:	5.5	
Meltin	g point/freezing point	:	No data avail	able
Initial range	boiling point and boiling	:	No data avail	able
Flash	point	:	No data avail	able
Evapo	oration rate	:	No data avail	able
Flamn	nability (solid, gas)	:	Not applicabl	e
Flamn	nability (liquids)	:	No data avail	able
	r explosion limit / Upper ability limit	:	No data avail	able
	r explosion limit / Lower ability limit	:	No data avail	able
Vapoι	ur pressure	:	No data avail	able
Relati	ve vapour density	:	No data avail	able
Relati	ve density	:	No data avail	able
	ility(ies) ater solubility	:	soluble	
	on coefficient: n-	:	No data avail	able
	ol/water gnition temperature	:	No data avail	able
Decor	nposition temperature	:	No data avail	able



Golimumab Formulation

Reactivity:Not classified as a reactivity hazard.Chemical stability:Stable under normal conditions.Possibility of hazardous reactions:Can react with strong oxidizing agents.Conditions to avoid:None known.Incompatible materials:Oxidizing agentsHazardous decomposition products:No hazardous decomposition products are known.	sion	Revision Date: 28.09.2024	SDS Number: 26446-00026	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014
Explosive properties : Not explosive Oxidizing properties : The substance or mixture is not classified as oxidizing. Molecular weight : No data available Particle characteristics : No data available Particle characteristics : No data available Particle size : No data available totn 10: Stability and reactivity : Stable under normal conditions. Chemical stability : Stable under normal conditions. Possibility of hazardous reactivits : Stable under normal conditions. Conditions to avoid : None known. Incompatible materials : Oxidizing agents Hazardous decomposition : Nohe known. Incompatible materials : Oxidizing agents Hazardous decomposition : Nohe known. Incompatible materials : Oxidizing agents Hazardous decomposition : Noh azardous decomposition products are known. products : Noh azardous decomposition products are known. Exposure routes : Inhalation Skin cortact : Ingestion Lyce contact : Ingestion Stable dased on available information. Serious eye damage/eye irritation <t< td=""><td></td><td></td><td></td><td></td></t<>				
Oxidizing properties : The substance or mixture is not classified as oxidizing. Molecular weight : No data available Particle characteristics : No data available Particle size : No data available toton 10: Stability and reactivity : Stable under normal conditions. Chemical stability : Stable under normal conditions. Possibility of hazardous reactivity : Can react with strong oxidizing agents. Conditions to avoid : None known. Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous decomposition products are known. products : None known. total stability decomposition : Oxidizing agents Hazardous decomposition : No hazardous decomposition products are known. products : No hazardous decomposition products are known. total 11: Toxicological information Skin contact Ingestion Eye contact Acute toxicity : Inhalation Skin corrosion/irritation : Skin contact Not classified based on available information. : Staperatory or skin sensitisation Not classified based on available information. : Staperatory or skin sensitisation Not classified based on availa	Visc	cosity, kinematic	: No data availa	ble
Molecular weight : No data available Particle characteristics Particle size : No data available Particle size : No data available tion 10: Stability and reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions. Possibility of hazardous reac- tions : Can react with strong oxidizing agents. Conditions to avoid : None known. Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous decomposition products are known. products : None known. tion 11: Toxicological information : Skin contact Exposure routes : Inhalation Skin contact Skin contact Ingestion Eye contact : 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. : <td>Explosi</td> <td>ve properties</td> <td>: Not explosive</td> <td></td>	Explosi	ve properties	: Not explosive	
Particle size : No data available Particle size : No data available tion 10: Stability and reactivity Reactivity : 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 tion 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. Skin corrosion/irritation Not classified based on available information. Skin sensitisation Not classified based on available information. Skin sensitisation Not classified based on available information. Skin sensitisation Not classified based on available information. Respiratory or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Components: Golimumab: Exposure routes : Inhalation	Oxidiziı	ng properties	: The substance	or mixture is not classified as oxidizing.
Particle size : No data available stion 10: Stability and reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions. Possibility of hazardous reactivity : Can react with strong oxidizing agents. tions : Oxidizing agents Conditions to avoid : None known. Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous decomposition products are known. products : None known. ettion 11: Toxicological information : No hazardous decomposition products are known. ettion 11: Toxicological information : Skin contact lngestion Eye contact Exposure routes : Inhalation Skin contact lngestion Eye contact 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 Not classified based on available information. : Respiratory sensitisation Not classified based on available information. : Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. : Components:	Molecu	lar weight	: No data availa	ble
Chemical stability : Stable under normal conditions. Possibility of hazardous reactions : Can react with strong oxidizing agents. tions : None known. Incompatible materials : Oxidizing agents Hazardous decomposition : None known. products : No hazardous decomposition products are known. products : Inhalation Skin contact Ingestion Eye contact Acute toxicity : Inhalation. Skin corrosion/irritation : Not classified based on available information. Serious eye damage/eye irritation : Not classified based on available information. Respiratory or skin sensitisation : Not classified based on available information. Respiratory sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. </td <td></td> <td></td> <td>: No data availa</td> <td>ble</td>			: No data availa	ble
Chemical stability : Stable under normal conditions. Possibility of hazardous reactions : Can react with strong oxidizing agents. tions : None known. Incompatible materials : Oxidizing agents Hazardous decomposition : None known. products : No hazardous decomposition products are known. products : Inhalation Skin contact Ingestion Eye contact Acute toxicity : Inhalation. Skin corrosion/irritation : Not classified based on available information. Serious eye damage/eye irritation : Not classified based on available information. Respiratory or skin sensitisation : Not classified based on available information. Respiratory sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. </td <td>tion 10:</td> <td>Stability and reactivi</td> <td>ty</td> <td></td>	tion 10:	Stability and reactivi	ty	
Possibility of hazardous reac- tions : Can react with strong oxidizing agents. Conditions to avoid : None known. Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous decomposition products are known. products : No hazardous decomposition products are known. tion 11: Toxicological information : No hazardous decomposition products are known. 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 or skin sensitisation Not classified based on available information. Respiratory or skin sensitisation Not classified based on available information. Respiratory or skin sensitisation Not classified based on available information. Respiratory or skin sensitisation Not classified based on available information. Respiratory or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Components: <t< td=""><td></td><td></td><td></td><td></td></t<>				
tions Conditions to avoid : None known. Incompatible materials : Oxidizing agents Hazardous decomposition products are known. products etion 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 or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Components: Golimumab: Exposure routes : Inhalation				
Conditions to avoid : None known. Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous decomposition products are known. products : No hazardous decomposition products are known. trion 11: Toxicological information : No hazardous decomposition products are known. 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 Skin sensitisation : Not classified based on available information. Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. Components: : Exposure routes : Inhalation		inty of nazardous reac-	: Can react with	strong oxidizing agents.
Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous decomposition products are known. products : No hazardous decomposition products are known. trion 11: Toxicological information : Inhalation Exposure routes : Inhalation Skin contact Ingestion 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 or skin sensitisation . May cause allergy or asthma symptoms or breathing difficulties if inhaled. . Components: . Golimumab: . . Exposure routes : .		ons to avoid	: None known.	
Hazardous decomposition : No hazardous decomposition products are known. products : Inhalation Exposure routes : Inhalation Skin contact Ingestion Eye contact : Eye contact Acute toxicity : No hazardous decomposition products are known. Not classified based on available information. : Skin contact Skin corrosion/irritation : No t classified based on available information. Serious eye damage/eye irritation : No t 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. : Respiratory or skin sensitisation Not classified based on available information. : Respiratory or skin sensitisation Not classified based on available information. : Respiratory sensitisation Not classified based on available information. : Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. : Components: Golimumab: : Inhalation				nts
retion 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. Serious eye damage/eye irritation Not classified based on available information. Respiratory or skin sensitisation Skin sensitisation Not classified based on available information. Respiratory or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Components: Golimumab: Exposure routes : Inhalation				
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. Serious eye damage/eye 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. Components: Golimumab: Exposure routes : Inhalation	Hazard		: No hazardous	decomposition products are known.
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. Serious eye damage/eye irritation Not classified based on available information. Respiratory or skin sensitisation Skin sensitisation Not classified based on available information. Respiratory or skin sensitisation Not classified based on available information. Respiratory or 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	Hazard		: No hazardous	decomposition products are known.
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	Hazard product	ts		decomposition products are known.
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	Hazard product tion 11:	ts Toxicological inform	ation	decomposition products are known.
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 or skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Golimumab: Exposure routes Inhalation	Hazard product tion 11:	ts Toxicological inform	ation : Inhalation Skin contact	decomposition products are known.
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 or skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Respiratory 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	Hazard product tion 11:	ts Toxicological inform	ation : Inhalation Skin contact Ingestion	decomposition products are known.
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 or skin sensitisation Not classified based on available information. Respiratory 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	Hazard product tion 11:	ts Toxicological inform	ation : Inhalation Skin contact Ingestion	decomposition products are known.
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 or 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	Hazard product tion 11: Exposu	ts Toxicological inform	ation : Inhalation Skin contact Ingestion	decomposition products are known.
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	Hazard product tion 11: Exposu	ts Toxicological inform are routes toxicity	ation : Inhalation Skin contact Ingestion Eye contact	decomposition products are known.
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	Hazard product tion 11: Exposu Acute to Not class	ts Toxicological inform ire routes toxicity ssified based on availa	ation : Inhalation Skin contact Ingestion Eye contact	decomposition products are known.
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	Hazard product tion 11: Exposu Acute 1 Not clas Skin co	ts Toxicological inform are routes toxicity ssified based on availa prrosion/irritation	ation : Inhalation Skin contact Ingestion Eye contact ble information.	decomposition products are known.
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	Hazard product tion 11: Exposu Acute to Not class Not class	ts Toxicological inform are routes toxicity ssified based on availa prrosion/irritation ssified based on availa	ation : Inhalation Skin contact Ingestion Eye contact ble information. ble information.	decomposition products are known.
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	Hazard product tion 11: Exposu Acute t Not clas Skin co Not clas Serious	ts Toxicological inform are routes toxicity ssified based on availa prrosion/irritation ssified based on availa s eye damage/eye irri	ation : Inhalation Skin contact Ingestion Eye contact ble information. ble information. tation	decomposition products are known.
Not classified based on available information. Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Components: Golimumab: Exposure routes : Inhalation	Hazard product tion 11: Exposu Acute to Not class Serious Not class	ts Toxicological inform are routes toxicity ssified based on availa prrosion/irritation ssified based on availa s eye damage/eye irri ssified based on availa	ation : Inhalation Skin contact Ingestion Eye contact ble information. ble information. tation ble information.	decomposition products are known.
May cause allergy or asthma symptoms or breathing difficulties if inhaled. Components: Golimumab: Exposure routes : Inhalation	Hazard product tion 11: Exposu Acute to Not class Serious Not class Respire	ts Toxicological inform are routes toxicity ssified based on availa prosion/irritation ssified based on availa s eye damage/eye irri ssified based on availa atory or skin sensitis	ation : Inhalation Skin contact Ingestion Eye contact ble information. ble information. tation ble information.	decomposition products are known.
Components: Golimumab: Exposure routes : Inhalation	Hazard product tion 11: Exposu Acute to Not class Serious Not class Respira Skin se	ts Toxicological inform are routes toxicity ssified based on availa prrosion/irritation ssified based on availa s eye damage/eye irri ssified based on availa atory or skin sensitist ensitisation	ation : Inhalation Skin contact Ingestion Eye contact ble information. tation ble information. tation	decomposition products are known.
Exposure routes : Inhalation	Hazard product tion 11: Exposu Acute t Not clas Skin co Not clas Respira Skin se Not clas Respira	ts Toxicological inform are routes toxicity ssified based on availa prosion/irritation ssified based on availa s eye damage/eye irri ssified based on availa atory or skin sensitist ensitisation ssified based on availa atory sensitisation	ation : Inhalation Skin contact Ingestion Eye contact ble information. tation ble information. ation ble information.	
	Hazard product tion 11: Exposu Acute t Not clas Skin co Not clas Respira Skin so Not clas Respira May ca	ts Toxicological inform are routes toxicity ssified based on availa prosion/irritation ssified based on availa s eye damage/eye irri ssified based on availa atory or skin sensitist ensitisation ssified based on availa atory sensitisation use allergy or asthma s	ation : Inhalation Skin contact Ingestion Eye contact ble information. tation ble information. ation ble information.	
	Hazard product tion 11: Exposu Acute t Not clas Skin co Not clas Serious Not clas Respira May ca Compo	ts Toxicological inform are routes toxicity ssified based on availa prosion/irritation ssified based on availa s eye damage/eye irri ssified based on availa atory or skin sensitist ensitisation ssified based on availa atory sensitisation use allergy or asthma soments:	ation : Inhalation Skin contact Ingestion Eye contact ble information. tation ble information. ation ble information.	
	Hazard product tion 11: Exposu Acute of Not class Skin co Not class Respira Skin se Not class Respira May ca Compo Golimu	ts Toxicological inform are routes toxicity ssified based on availa prosion/irritation ssified based on availa atory or skin sensitist ensitisation ssified based on availa atory sensitisation use allergy or asthma sonents: umab:	ation : Inhalation Skin contact Ingestion Eye contact ble information. tation ble information. ation ble information. symptoms or breath	



Golimumab Formulation

ersion 2	Revision Date: 28.09.2024	SDS Number: 26446-00026	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014
Chro	nic toxicity		
Germ	cell mutagenicity lassified based on ava	ailable information.	
	nogenicity lassified based on ava	ailable information.	
	oductive toxicity lassified based on ava	ailable information.	
Com	oonents:		
Golin	numab:		
Effect	ts on fertility	Species: Mous Application Ro	tility/early embryonic development e, male ute: Intravenous injection EL Parent: 40 mg/kg body weight
		Species: Mous Application Ro	tility/early embryonic development se, female ute: Intravenous injection EL Parent: 40 mg/kg body weight
Effect ment	ts on foetal develop-	Species: Monk Teratogenicity:	bryo-foetal development cey NOAEL: 100 mg/kg body weight toxicity: NOAEL: 100 mg/kg body weight
		Test Type: Dev Species: Monk Developmenta	
		Species: Mous Application Ro Teratogenicity Embryo-foetal	bryo-foetal development e ute: Intravenous injection NOAEL: 40 mg/kg body weight toxicity: NOAEL: 40 mg/kg body weight ve, No effects on foetal development
	- single exposure	hilphla information	
	lassified based on ava		

Not classified based on available information.

Repeated dose toxicity

Components:

Golimumab:

Species

: Monkey



Golimumab Formulation

ersion 2	Revision Date: 28.09.2024	SDS Number: 26446-00026	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014
		50 //	
NOAI Appli	EL cation Route	: 50 mg/kg : Intravenous	
	sure time	: 6 Months	
	per of exposures	: Intermittent	
Spec		: Monkey	
NOA		: 25 mg/kg	
	cation Route sure time	: Subcutaneous : 6 Months	
Spec	ies	: Mouse	
NOA		: 40 mg/kg	
Appli	cation Route	: Intravenous	
Com	ponents:		
Golin	numab:		
Inhala	ation		Id infections, upper respiratory tract infection, , bronchitis, sinusitis, fungal infections
ection 1	2: Ecological informati	on	
Ecote	oxicity		
Com	ponents:		
Golin	numab:		
Ecote	oxicology Assessment		
Acute	aquatic toxicity	: No data availa	ble
Chror	nic aquatic toxicity	: No data availa	ble
Dara	stence and degradabil	4.,	
Persi	stence and degradable	lv	

No data available

Bioaccumulative potential

No data available

Mobility in soil No data available

Other adverse effects

No data available



Golimumab Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.09.2023
7.2	28.09.2024	26446-00026	Date of first issue: 29.10.2014

Section 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.	

Section 14: Transport information

International Regulations

UNRTDG UN number Proper shipping name Class Subsidiary risk Packing group Labels Environmentally hazardous		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)	:	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IMDG-Code UN number Proper shipping name Class Subsidiary risk Packing group	:	Not applicable Not applicable Not applicable Not applicable Not applicable

Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable for product as supplied.

National Regulations

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



Golimumab Formulation

Version 7.2	Revision Date: 28.09.2024	SDS Number: 26446-00026	Date of last issue: 29.09.2023 Date of first issue: 29.10.2014	
Pack Labe	idiary risk ing group Is hem Code	Not applicableNot applicableNot applicableNot applicableNot applicable		
-	al precautions for u	ser		

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

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

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 Agency, 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



Golimumab Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.09.2023
7.2	28.09.2024	26446-00026	Date of first issue: 29.10.2014

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 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.

NZ / EN