

according to the Globally Harmonized System

Infliximab Formulation

Version 2.2	Revision Date: 28.09.2024	SDS Number: 19275-00022	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Infliximab Formulation
Manufacturer or supplier's de Company	eta :	ils MSD
Address	:	Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207
Telephone	:	+1-908-740-4000
Emergency telephone number	:	+1-908-423-6000
E-mail address	:	EHSDATASTEWARD@msd.com
Recommended use of the ch	em	ical and restrictions on use
Recommended use Restrictions 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

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 70 - < 90
Infliximab	170277-31-3	>= 10 - < 20

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. FIRST	AID MEASURES					
General advice		:	vice immediate	accident or if you feel unwell, seek medical ad ely. ms persist or in all cases of doubt seek medica		
If inhaled		:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.			
In case of skin contact		:	Wash with wa			
In case of eye contact		:		e well with water. Itention if irritation develops and persists.		
If swallowed		:	Get medical a	DO NOT induce vomiting. ttention if symptoms occur. horoughly with water.		
Most important symptoms and effects, both acute and		:	Contact with d the skin.	ust can cause mechanical irritation or drying c		
delayed Protection of first-aiders Notes to physician		:	No special pre	ecautions are necessary for first aid responders natically and supportively.		
. FIREFI	GHTING MEASURES					
Suitable extinguishing media		:	Water spray Alcohol-resista	ant foam		

		Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances 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.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if nec- essary. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Follow safe handling advice (see section 7) and personal pro-



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		uipment and emer- procedures		tective equipment	recommendations (see section 8).
	Enviror	nmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
	Methods and materials for : containment and cleaning up		:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

7. HANDLING AND STORAGE

Technical measures	 Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation Advice on safe handling	 Use only with adequate ventilation. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	



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Sucro			57-50-1 170277-31-3	TWA TWA	10 mg/m3 150 µg/m3	ACGIH	
Infilxi	map		1/02/7-31-3	IVVA	150 µg/m3	Internal	
Engi	neering measures	:	Minimize work Apply measur Ensure that du dust collectors signed in a ma	xplace exposur es to prevent d ust-handling sy s, vessels, and anner to prever	especially in confine e concentrations. lust explosions. stems (such as exha processing equipmen nt the escape of dust e from the equipment	ust ducts, nt) are de- into the work	
Perse	onal protective equip	ment	t				
Fi	iratory protection Iter type protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type				
M	aterial	:	Chemical-resi	stant gloves			
Re	emarks	:	For prolonged Wash hands b	l or repeated co before breaks a	ontact use protective and at the end of work	gloves. day.	
Eye p	protection	:	: Wear the following personal protective equipment: Safety goggles				
Skin	and body protection	:	Skin should be washed after contact.				
Hygie	ene measures	:	flushing syste place. When using d	ms and safety o not eat, drink	ely during typical use showers close to the cor smoke. before re-use.		

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Am	orphous powder
Colour	: whi	ite
Odour	: No	data available
Odour Threshold	: No	data available
рН	: 7.2	
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



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Flam	mability (solid, gas)	:	May form expl dling or other	osive dust-air mixture during processing, han- means.
Flam	mability (liquids)	:	No data availa	ble
	r explosion limit / Upper nability limit	:	No data availa	ble
	r explosion limit / Lower nability limit	:	No data availa	ble
Vapo	ur pressure	:	No data availa	ble
Relat	ive vapour density	:	No data availa	ble
Relat	ive density	:	No data availa	ble
Dens	ity	:	1 g/cm ³	
	bility(ies) ater solubility	:	No data availa	ble
	ion coefficient: n- ol/water	:	No data availa	ble
	ignition temperature	:	No data availa	ble
Deco	mposition temperature	:	No data availa	ble
Visco Vi	sity scosity, kinematic	:	No data availa	ble
Explo	sive properties	:	Not explosive	
Oxidi	zing properties	:	The substance	e or mixture is not classified as oxidizing.
Moleo	cular weight	:	No data availa	ble
	cle characteristics cle size	:	No data availa	ble

10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition	:	Oxidizing agents



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ersion 2	Revision Date: 28.09.2024		OS Number: 275-00022	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
produ	ucts			
. TOXIC	COLOGICAL INFORM		N	
Inforr expos	nation on likely routes sure	of :	Inhalation Skin contact Ingestion Eye contact	
	e toxicity			
	lassified based on ava	ilable	information.	
	ponents:			
Sucr Acute	ose: e oral toxicity	:	LD50 (Rat): 29),700 mg/kg
-	corrosion/irritation lassified based on ava	ilable	information.	
Com	ponents:			
Inflix Rema	imab: arks		No data availa	ble
Soria	ous eye damage/eye i	rritati	on	
	lassified based on ava			
Com	ponents:			
Inflix	imab:			
Rema	arks	:	No data availa	ble
Resp	iratory or skin sensit	isatio	on	
-	sensitisation lassified based on ava	ilable	information.	
-	iratory sensitisation lassified based on ava	ilable	information.	
	n cell mutagenicity lassified based on ava	ilable	information.	
Com	ponents:			
Sucr	ose:			

Infliximab:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative



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		:	Test system: hum Result: negative	nosomal aberration nan lymphoblastoid cells	
Genc	Genotoxicity in vivo		Test Type: Micronucleus test Species: Mouse Method: OECD Test Guideline 474 Result: negative		
	n cell mutagenicity - ssment	:	Weight of evidence does not support classification as a germ cell mutagen.		
Not c Repr Not c	inogenicity lassified based on availa oductive toxicity lassified based on availa				
	ponents:				
	imab: ts on fertility	:	Fertility: NOAEL:	y e: Intravenous injection 40 mg/kg body weight on data from similar materials	
	Effects on foetal develop- ment		Test Type: Embryo-foetal development Species: Mouse, female Application Route: Intravenous injection Duration of Single Treatment: 6 - 12 d General Toxicity Maternal: NOAEL: 40 mg/kg body weight Teratogenicity: NOAEL F1: 40 mg/kg body weight Developmental Toxicity: NOAEL F1: 40 Embryo-foetal toxicity: NOAEL: 40 mg/kg body weight Remarks: Based on data from similar materials		
	Γ - single exposure lassified based on avail	able	information.		
	F - repeated exposure lassified based on availa	able	information.		
Repe	eated dose toxicity				

Components:

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	ration toxicity lassified based on availa	ahle	information		
	rience with human exp				
Com	ponents:				
Inflix	imab:				
Inhal	ation	:	Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, Fatigue, Headache, Back pain		
2. ECOL	OGICAL INFORMATIO	N			
Ecot	oxicity				
<u>Com</u>	ponents:				
Inflix	imab:				
	oxicology Assessment e aquatic toxicity	:	No data available	e	
Chro	nic aquatic toxicity	:	No data available	e	
	istence and degradabil ata available	ity			
Bioa	ccumulative potential				
<u>Com</u>	ponents:				
	ose: tion coefficient: n- nol/water	:	Pow: < 1		
	i lity in soil ata available				
	r adverse effects ata available				
13. DISPO	SAL CONSIDERATION	١S			
Disp	osal methods				
\M/oot	e from residues		Do not dianago o	f wasta into sowar	

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/		
Date format	:	dd.mm.yyyy		
Full text of other abbreviations				
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)		
ACGIH / TWA	:	8-hour, time-weighted average		

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 Sys-

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tem; 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.

IN / EN