

according to the Hazardous Products Regulations

Infliximab Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
2.2	09/28/2024	19261-00024	Date of first issue: 10/07/2014

SECTION 1. IDENTIFICATION

Product name	:	Infliximab Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

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

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Sucrose	.alphaD- Glucopyra- noside, .beta D- fructofuranosyl	57-50-1	>= 80 - <= 100 *
Infliximab	No data availa- ble	170277-31-3	>= 10 - < 30 *

* Actual concentration or concentration range is withheld as a trade secret

:

SECTION 4. FIRST AID MEASURES

General advice

In the case of accident or if you feel unwell, seek medical advice immediately.

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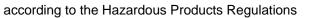
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		When sympto advice.	ms persist or in all cases of doubt seek medical
If inf	naled	: If inhaled, ren	nove to fresh air.
		Get medical a	ttention if symptoms occur.
In ca	ase of skin contact	: Wash with wa	•
			ttention if symptoms occur.
In ca	ase of eye contact		se well with water.
			Ittention if irritation develops and persists.
If sw	allowed		DO NOT induce vomiting.
			Ittention if symptoms occur.
			horoughly with water.
	t important symptoms		dust can cause mechanical irritation or drying of
	effects, both acute and	the skin.	
dela			with the eyes can lead to mechanical irritation.
Prot	ection of first-aiders		ecautions are necessary for first aid responders.
Note	es to physician	: Treat symptor	matically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray 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 fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment.





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			Retain and dispo	eakage or spillage if safe to do so. ose of contaminated wash water. s should be advised if significant spillages ined.
Methods and materials for : containment and cleaning up		container for dis Avoid dispersal with compressed Dust deposits sh surfaces, as the released into the Local or national disposal of this r employed in the determine which Sections 13 and	of dust in the air (i.e., clearing dust surfaces	

SECTION 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	: Use only with adequate ventilation.
Advice on safe handling	: 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 labeled containers.
C C	Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m ³	CA AB OEL
		TWA (Total	10 mg/m ³	CA BC OEL
		dust)	-	



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				TWA (respir- able dust fraction)	3 mg/m³	CA BC OE
				TWAEV	10 mg/m ³	CA QC OE
				TWA	10 mg/m ³	ACGIH
Inflixir	nab		170277-31-3	TWA	150 µg/m³	Internal
Engir	neering measures	:	Minimize worl Apply measur Ensure that d dust collectors designed in a	kplace exposure res to prevent du ust-handling sys s, vessels, and p manner to preve	especially in confine concentrations. ust explosions. stems (such as exhap processing equipme ent the escape of d akage from the equi	aust ducts, ent) are ust into the
Perso	onal protective equip	ment				
Fil	iratory protection ter type protection	:	exposure ass	essment demon d guidelines, use	tilation is not availa strates exposures o e respiratory protect	outside the
Ma	aterial	:	Chemical-res	istant gloves		
Re	emarks	:			ntact use protective nd at the end of wor	
	rotection	:	Safety goggle	S	protective equipmen	t:
	and body protection ne measures	:	If exposure to eye flushing s working place When using d	systems and safe	ly during typical use ety showers close to or smoke.	
CTION	9. PHYSICAL AND C	HEMI	CAL PROPER	TIES		
Appea	arance	:	Amorphous p	powder		
Color			white			

Color	:	white
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	7.2
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available

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	Flash p	point	:	No data available	
	Evapor	ration rate	:	No data available)
	Flamm	ability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.
	Flamm	ability (liquids)	:	No data available)
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	
	Vapor	pressure	:	No data available)
	Relativ	e vapor density	:	No data available)
	Relativ	e density	:	No data available)
	Density	/	:	1 g/cm ³	
	Solubil Wat	ity(ies) ter solubility	:	No data available)
	Partitio octano	n coefficient: n-	:	No data available)
		nition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	Viscosi Visc	ity cosity, kinematic	:	No data available)
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available)
	Particle Particle	e characteristics e size	:	No data available	

SECTION 10. STABILITY AND REACTIVITY

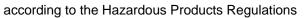
Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing,
tions		handling or other means.
		Can react with strong oxidizing agents.

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ln H pr	onditions to avoid compatible materials azardous decompositio roducts	tion : No hazardous decomposition products are known.		
SECT	ON 11. TOXICOLOGIC	AL INFORMATION		
In Si In	formation on likely ro halation kin contact gestion ye contact	utes of exposure		
	cute toxicity ot classified based on a	vailable information.		
<u>c</u>	omponents:			
	ucrose: cute oral toxicity	: LD50 (Rat): 29,7	700 mg/kg	
-	kin corrosion/irritation ot classified based on a			
<u>c</u>	omponents:			
	fliximab: emarks	: No data availabl	e	
Ν	erious eye damage/ey ot classified based on a			
	omponents:			
	f liximab: emarks	: No data availabl	e	
R	espiratory or skin ser	sitization		
-	kin sensitization ot classified based on a	vailable information.		
	espiratory sensitization of classified based on a			
	erm cell mutagenicity ot classified based on a			
<u>c</u>	omponents:			
-	ucrose: enotoxicity in vitro	: Test Type: In vit Result: negative	ro mammalian cell gene mutation test	
		6 / 11		





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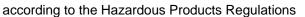
ersion .2	Revision Date: 09/28/2024		S Number: 261-00024	Date of last issue: 09/26/2023 Date of first issue: 10/07/2014
Inflix	imab:			
Geno	otoxicity in vitro	:		cterial reverse mutation assay (AMES) D Test Guideline 471 ve
				romosomal aberration numan lymphoblastoid cells ve
Geno	otoxicity in vivo	:	Species: Mous	D Test Guideline 474
	n cell mutagenicity - ssment	:	Weight of evid cell mutagen.	lence does not support classification as a gern
	inogenicity lassified based on avai	ilable i	nformation.	
	oductive toxicity classified based on avai	ilable i	nformation.	
<u>Com</u>	ponents:			
	t imab: Its on fertility	:	Fertility: NOAE	
Effec	ts on fetal developmen	t :	Species: Mous Application Rc Duration of Sir General Toxic Teratogenicity Developmenta Embryo-fetal t	nbryo-fetal development se, female oute: Intravenous injection ngle Treatment: 6 - 12 d ity Maternal: NOAEL: 40 mg/kg body weight : NOAEL F1: 40 mg/kg body weight al Toxicity: NOAEL F1: 40 oxicity.: NOAEL: 40 mg/kg body weight ed on data from similar materials

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.





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Repeated dose toxicity

Components:

Infliximab:

:	Mouse
:	40 mg/kg
:	Intravenous
:	6 Months
:	daily
	:

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Infliximab:

Inhalation

: Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhea, Fatigue, Headache, Back pain

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Infliximab:

Ecotoxicology Assessment

Acute aquatic toxicity	:	No data available
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Chronic aquatic toxicity : No data available

Persistence and degradability

No data available

Bioaccumulative potential

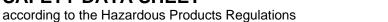
Components:

Sucrose: Partition coefficient: n- : Pow: < 1 octanol/water

Mobility in soil

No data available

Other adverse effects No data available





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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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:			
AICS	:	not determined	
DSL	:	not determined	
IECSC	:	not determined	

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safe- ty, Schedule 1, Part 1: Permissible exposure values for air-

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	borne contaminants
ACGIH / TWA	: 8-hour, time-weighted average
CA AB OEL / TWA	: 8-hour Occupational exposure limit
CA BC OEL / TWA	: 8-hour time weighted average
CA QC OEL / TWAEV	: Time-weighted average exposure value

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 - 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 - Verv Persistent and Verv Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material 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/
Revision Date Date format	:	09/28/2024 mm/dd/yyyy

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



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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.

CA / Z8