

# SAFETY DATA SHEET



## Infliximab Formulation

Version 2.2 Revision Date: 28.09.2024 SDS Number: 19252-00024 Date of last issue: 26.09.2023 Date of first issue: 07.10.2014

---

### SECTION 1. IDENTIFICATION

Product name : Infliximab Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor  
Buenos Aires, Argentina C1001AFB

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### SECTION 2. HAZARDS IDENTIFICATION

#### 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.

---

### SECTION 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

---

### SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

# SAFETY DATA SHEET



## Infliximab Formulation

Version 2.2	Revision Date: 28.09.2024	SDS Number: 19252-00024	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
----------------	------------------------------	----------------------------	---

If inhaled	: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	: Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	: No special precautions are necessary for first aid responders.
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 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 products	: Carbon oxides
Specific extinguishing methods	: 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.
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, protective equipment and emergency procedures	: Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages

# SAFETY DATA SHEET



## Infliximab Formulation

Version  
2.2

Revision Date:  
28.09.2024

SDS Number:  
19252-00024

Date of last issue: 26.09.2023  
Date of first issue: 07.10.2014

cannot be contained.

Methods and materials for containment and cleaning up

- : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## 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.

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	CMP	10 mg/m <sup>3</sup>	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
Infliximab	170277-31-3	TWA	10 mg/m <sup>3</sup>	ACGIH
			150 µg/m <sup>3</sup>	Internal

Engineering measures

- : Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.

# SAFETY DATA SHEET



## Infliximab Formulation

Version  
2.2

Revision Date:  
28.09.2024

SDS Number:  
19252-00024

Date of last issue: 26.09.2023  
Date of first issue: 07.10.2014

Apply measures to prevent dust explosions.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

### Personal protective equipment

Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	: Particulates type
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: For prolonged or repeated contact use protective gloves. Wash hands before breaks and at the end of workday.
Eye protection	: Wear the following personal protective equipment: Safety goggles
Skin and body protection	: Skin should be washed after contact.
Hygiene measures	: 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Amorphous powder
Color	: white
Odor	: No data available
Odor Threshold	: No data available
pH	: 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
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: No data available
Upper explosion limit / Upper	: No data available

# SAFETY DATA SHEET



## Infliximab Formulation

Version 2.2 Revision Date: 28.09.2024 SDS Number: 19252-00024 Date of last issue: 26.09.2023 Date of first issue: 07.10.2014

---

### flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1 g/cm<sup>3</sup>

### Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

### Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

### Particle characteristics

Particle 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 reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

---

## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion

# SAFETY DATA SHEET



## Infliximab Formulation

Version 2.2	Revision Date: 28.09.2024	SDS Number: 19252-00024	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
----------------	------------------------------	----------------------------	---

---

Eye contact

### Acute toxicity

Not classified based on available information.

### Components:

#### **Sucrose:**

Acute oral toxicity : LD50 (Rat): 29.700 mg/kg

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### **Infliximab:**

Remarks : No data available

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### **Infliximab:**

Remarks : No data available

### Respiratory or skin sensitization

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

#### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **Sucrose:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

#### **Infliximab:**

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

Test Type: Chromosomal aberration  
Test system: human lymphoblastoid cells  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Method: OECD Test Guideline 474

# SAFETY DATA SHEET



## Infliximab Formulation

Version 2.2	Revision Date: 28.09.2024	SDS Number: 19252-00024	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
----------------	------------------------------	----------------------------	---

Result: negative

**Germ cell mutagenicity - Assessment** : Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Not classified based on available information.

#### Components:

##### **Infliximab:**

Effects on fertility : Test Type: Fertility  
Species: Mouse  
Application Route: Intravenous injection  
Fertility: NOAEL: 40 mg/kg body weight  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal 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-fetal toxicity: NOAEL: 40 mg/kg body weight  
Remarks: Based on data from similar materials

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### **Infliximab:**

Species : Mouse  
NOAEL : 40 mg/kg  
Application Route : Intravenous  
Exposure time : 6 Months  
Number of exposures : daily

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **Infliximab:**

# SAFETY DATA SHEET



## Infliximab Formulation

Version 2.2	Revision Date: 28.09.2024	SDS Number: 19252-00024	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
----------------	------------------------------	----------------------------	---

---

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

Chronic aquatic toxicity : No data available

#### Persistence and degradability

No data available

#### Bioaccumulative potential

#### Components:

##### Sucrose:

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

#### Mobility in soil

No data available

#### Other adverse effects

No data available

---

## 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

# SAFETY DATA SHEET



## Infliximab Formulation

Version 2.2 Revision Date: 28.09.2024 SDS Number: 19252-00024 Date of last issue: 26.09.2023 Date of first issue: 07.10.2014

---

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

Not applicable for product as supplied.

### Special precautions for user

Not applicable

---

## SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

### The ingredients 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  
Date format : dd.mm.yyyy

### Further information

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 Agency, <http://echa.europa.eu/>

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

AR OEL / CMP : TLV (Threshold Limit 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 Chemi-

# SAFETY DATA SHEET



## Infliximab Formulation

Version  
2.2

Revision Date:  
28.09.2024

SDS Number:  
19252-00024

Date of last issue: 26.09.2023  
Date of first issue: 07.10.2014

cal Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - 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.

AR / Z8