

**Infliximab Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 26.09.2023  |
| 2.2     | 28.09.2024     | 19280-00022 | Date of first issue: 07.10.2014 |

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Infliximab Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD  
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@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**

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.

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.

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|                                                             |   |                                                                                                                                                                                 |
|-------------------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Most important symptoms and effects, both acute and delayed | : | Rinse mouth thoroughly with water.<br>Contact with dust can cause mechanical irritation or drying of the skin.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | Wear self-contained breathing apparatus for firefighting if necessary.<br>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.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up               | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>Dust deposits should not be allowed to accumulate on  |

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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.<br>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.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures            | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.                                                                                                                                                                                                                  |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store in accordance with the particular national regulations.                                                                                                                                                                                                                                                                                                                                     |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents                                                                                                                                                                                                                                                                                                                                                                 |

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

| Components | CAS-No.     | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis             |
|------------|-------------|----------------------------------|------------------------------------------------|-------------------|
| Sucrose    | 57-50-1     | VLE-PPT                          | 10 mg/m <sup>3</sup>                           | NOM-010-STPS-2014 |
|            |             | TWA                              | 10 mg/m <sup>3</sup>                           | ACGIH             |
| Infliximab | 170277-31-3 | TWA                              | 150 µg/m <sup>3</sup>                          | Internal          |

- |                      |   |                                                                                                                                                                                                                                                                              |
|----------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Engineering measures | : | Ensure adequate ventilation, especially in confined areas.<br>Minimize workplace exposure concentrations.<br>Apply measures to prevent dust explosions.<br>Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are |
|----------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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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.

**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 flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

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|                                        |   |                                                          |
|----------------------------------------|---|----------------------------------------------------------|
| 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                                        |

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**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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.                                                                          |
| Incompatible materials             | : | Oxidizing agents                                                                                                           |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.                                                                             |

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

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**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: negativeTest Type: Chromosomal aberration  
Test system: human lymphoblastoid cells  
Result: negativeGenotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Method: OECD Test Guideline 474  
Result: negative

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

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**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Infliximab:**

|                              |   |                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility         | : | Test Type: Fertility<br>Species: Mouse<br>Application Route: Intravenous injection<br>Fertility: NOAEL: 40 mg/kg body weight<br>Remarks: Based on data from similar materials                                                                                                                                                                                                                                   |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Mouse, female<br>Application Route: Intravenous injection<br>Duration of Single Treatment: 6 - 12 d<br>General Toxicity Maternal: NOAEL: 40 mg/kg body weight<br>Teratogenicity: NOAEL F1: 40 mg/kg body weight<br>Developmental Toxicity: NOAEL F1: 40<br>Embryo-fetal toxicity.: NOAEL: 40 mg/kg body weight<br>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:**

|            |   |                                                                                       |
|------------|---|---------------------------------------------------------------------------------------|
| Inhalation | : | Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhea,<br>Fatigue, Headache, Back pain |
|------------|---|---------------------------------------------------------------------------------------|

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**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- : 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.<br>Dispose of in accordance with local regulations.                                                                        |
| Contaminated packaging | : Empty containers should be taken to an approved waste<br>handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

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**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**

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**NOM-002-SCT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, : Not applicable  
essential chemical products and machinery for  
producing capsules, tablets and pills.

**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

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting  
the Work Environment - Identification, Assessment and Con-  
trol - Appendix 1 Occupational Exposure Limits  
ACGIH / TWA : 8-hour, time-weighted average  
NOM-010-STPS-2014 / VLE- : Time weighted average limit value  
PPT

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

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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

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/>

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8