

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Infliximab Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/04/06  |
| 3.0     | 2024/09/28     | 19267-00023 | Date of first issue: 2014/10/07 |

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Infliximab Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road  
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

|            |                     |
|------------|---------------------|
| Appearance | : Amorphous powder  |
| Colour     | : white             |
| Odour      | : No data available |

Not a hazardous substance or mixture.

#### 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.

#### Physical and chemical hazards

Not classified based on available information.

#### Health hazards

Not classified based on available information.

#### Environmental hazards

Not classified based on available information.

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### 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     | $\geq 70$ -< 90       |
| Infliximab    | 170277-31-3 | $\geq 10$ -< 20       |

## 4. FIRST AID MEASURES

|                                                             |                                                                                                                                                          |
|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled                                                  | : If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur.                                                                           |
| In case of skin contact                                     | : Wash with water and soap.<br>Get medical attention if symptoms occur.                                                                                  |
| In case of eye contact                                      | : If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.                                                       |
| If swallowed                                                | : If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>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.<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.                                                                                                                |

## 5. FIREFIGHTING 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 prod-            | : Carbon oxides                                                                                                                                                                                                                 |

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ucts

- 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 firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

### 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 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.

### 7. HANDLING AND STORAGE

#### Handling

- 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.

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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.

Avoidance of contact : Oxidizing agents

### Storage

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

Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

| Components | CAS-No.     | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|------------|-------------|----------------------------------|------------------------------------------------|----------|
| Sucrose    | 57-50-1     | TWA                              | 10 mg/m3                                       | ACGIH    |
| Infliximab | 170277-31-3 | TWA                              | 150 µg/m3                                      | Internal |

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.  
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

Eye/face protection : Wear the following personal protective equipment:  
Safety goggles

Skin and body protection : Skin should be washed after contact.

Hand protection

Material : Chemical-resistant gloves

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|                  |                                                                                                                                                                                                                                    |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Remarks          | : For prolonged or repeated contact use protective gloves.<br>Wash hands before breaks and at the end of workday.                                                                                                                  |
| Hygiene measures | : If exposure to chemical is likely during typical use, provide<br>eye flushing systems and safety showers close to the work-<br>ing place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use. |

### 9. PHYSICAL AND CHEMICAL PROPERTIES

|                                                  |                                                                                   |
|--------------------------------------------------|-----------------------------------------------------------------------------------|
| Appearance                                       | : Amorphous powder                                                                |
| Colour                                           | : white                                                                           |
| Odour                                            | : No data available                                                               |
| Odour 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                                                               |
| Vapour pressure                                  | : No data available                                                               |
| Relative vapour density                          | : No data available                                                               |
| Relative density                                 | : No data available                                                               |
| Density                                          | : 1 g/cm <sup>3</sup>                                                             |
| Solubility(ies)<br>Water solubility              | : No data available                                                               |
| Partition coefficient: n-                        | : No data available                                                               |

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|                           |                                                            |
|---------------------------|------------------------------------------------------------|
| octanol/water             |                                                            |
| Auto-ignition 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                                        |

### 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.                                                                             |

### 11. TOXICOLOGICAL INFORMATION

|                 |                                                          |
|-----------------|----------------------------------------------------------|
| Exposure routes | : Inhalation<br>Skin contact<br>Ingestion<br>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.

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### 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 sensitisation**

##### **Skin sensitisation**

Not classified based on available information.

##### **Respiratory sensitisation**

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  
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.

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### 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 foetal development | : Test Type: Embryo-foetal 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-foetal 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, Diarrhoea, Fatigue, Headache, Back pain |
|------------|---------------------------------------------------------------------------------------|

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### 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

### 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.

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : Not applicable

Proper shipping name : Not applicable

Class : Not applicable

Subsidiary risk : Not applicable

Packing group : Not applicable

Labels : Not applicable

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Environmentally hazardous : no

### IATA-DGR

|                                          |                  |
|------------------------------------------|------------------|
| UN/ID No.                                | : Not applicable |
| Proper shipping name                     | : Not applicable |
| Class                                    | : Not applicable |
| Subsidiary risk                          | : Not applicable |
| Packing group                            | : Not applicable |
| Labels                                   | : Not applicable |
| Packing instruction (cargo aircraft)     | : Not applicable |
| Packing instruction (passenger aircraft) | : Not applicable |

### IMDG-Code

|                      |                  |
|----------------------|------------------|
| UN number            | : Not applicable |
| Proper shipping name | : Not applicable |
| Class                | : Not applicable |
| Subsidiary risk      | : Not applicable |
| Packing group        | : Not applicable |
| Labels               | : Not applicable |
| EmS Code             | : Not applicable |
| Marine pollutant     | : no             |

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

Not applicable for product as supplied.

### National Regulations

#### GB 6944/12268

|                      |                  |
|----------------------|------------------|
| UN number            | : Not applicable |
| Proper shipping name | : Not applicable |
| Class                | : Not applicable |
| Subsidiary risk      | : Not applicable |
| Packing group        | : Not applicable |
| Labels               | : Not applicable |
| Marine pollutant     | : no             |

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### Regulations on Safety Management of Hazardous Chemicals

|                                  |                                                                                                                                                                      |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Catalogue of Hazardous Chemicals | : This product is not listed in the catalogue of hazardous chemicals and it does not meet the definition of hazardous chemicals and its principles of determination. |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWS : Not listed

### Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

### Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

### Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

### 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 : 2024/09/28

### 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/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

### 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 -

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

### Disclaimer

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.

CN / EN