

Infliximab Formulation

| Version 2.2 | Revision Date: 2024/09/28 | | S Number: 272-00023 | Date of last issue: 2023/09/26 Date of first issue: 2014/10/07 |
|----------------|------------------------------------|------|--|---|
| | | | | |
| 1. PROD | OUCT AND COMPANY IDE | ENT | IFICATION | |
| Pro | duct name | : | Infliximab Formu | lation |
| Mai | nufacturer or supplier's d | leta | ils | |
| Cor | npany | : | MSD | |
| Ado | Iress | : | : 126 E. Lincoln Avenue Rahway, New Jersey U.S.A. 07065 | |
| Tele | ephone | : | 908-740-4000 | |
| Em | ergency telephone number | : | 1-908-423-6000 | |
| E-m | nail address | : | EHSDATASTEW | /ARD@msd.com |
| Rec | commended use of the ch | nem | ical and restriction | ons on use |
| | commended use strictions on use | : | Pharmaceutical Not applicable | |

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|-------------|-----------------------|
| Sucrose | 57-50-1 | >= 60 -<= 100 |
| Infliximab | 170277-31-3 | >= 10 -< 30 |

4. FIRST AID MEASURES



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| Gener | al advice | : | vice immediatel | ccident or if you feel unwell, seek medical ad- ly. as persist or in all cases of doubt seek medical | |
| lf inha | led | : | advice. If inhaled, remo | ve to fresh air. | |
| In cas | e of skin contact | : | Wash with wate | ention if symptoms occur. er and soap. ention if symptoms occur. | |
| In cas | e of eye contact | : | If in eyes, rinse | well with water. ention if irritation develops and persists. | |
| If swa | llowed | : | If swallowed, D | O NOT induce vomiting. ention if symptoms occur. | |
| and ef delaye Protec | mportant symptoms ffects, both acute and ed ction of first-aiders to physician | : | Rinse mouth the Contact with du the skin. Dust contact wi No special prec | oroughly with water. Ist can cause mechanical irritation or drying of th the eyes can lead to mechanical irritation. cautions are necessary for first aid responders. atically and supportively. | |
| FIREFIG | HTING MEASURES | | | | |
| Suitab | le extinguishing media | : | Water spray Alcohol-resistar Carbon dioxide Dry chemical | | |
| Unsuit media | table extinguishing | : | None known. | | |
| Specif fightin | fic hazards during fire- g | : | : Avoid generating dust; fine dust dispersed in air in suff concentrations, and in the presence of an ignition sour potential dust explosion hazard. Exposure to combustion products may be a hazard to | | |
| Hazar ucts | dous combustion prod- | : | Carbon oxides | | |
| Specif ods | fic extinguishing meth- | : | Use extinguishing measures that are appropriate to local c cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to so. Evacuate area. | | |
| | al protective equipment fighters | : | essary. | ained breathing apparatus for firefighting if nec rotective equipment. | |

6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protec- : | Follow safe handling advice (see section 7) and personal pro- |
|---------------------------------|---|
| tive equipment and emer- | tective equipment recommendations (see section 8). |



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| | gency | procedures | | | |
| | gonoy | procoduroo | | | |
| 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 | | : | tainer for disposa Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Local or national posal of this mate employed in the of mine which regula Sections 13 and | f dust in the air (i.e., clearing dust surfaces | |
| 7. HA | | NG AND STORAGE | | | |
| | Techni | cal measures | : | causing an explos | precautions, such as electrical grounding |
| | | otal ventilation on safe handling | Use only with adequate ventilation.Do not breathe dust. | | |

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Minimize dust generation and accumulation. Keep container closed when not in use.

| | | Reep 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 | ge : | Keep in properly labelled containers. |
| | | Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types: Strong oxidizing agents |
| | | |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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



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| | | | | - |

| | | exposure) | concentration | | | | |
|--|---|---|---------------|----------|--|--|--|
| Sucrose | 57-50-1 | NAB | 10 mg/m3 | ID OEL | | | |
| | enough data to | Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to hu- mans or animals | | | | | |
| | | TWA | 10 mg/m3 | ACGIH | | | |
| Infliximab | 170277-31-3 | TWA | 150 µg/m3 | Internal | | | |
| Engineering measures | Minimize work Apply measure Ensure that d dust collector signed in a m work area (i.e | 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 de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). | | | | | |
| Personal protective equipme | nt | | | | | | |
| Respiratory protection Filter type Hand protection | sure assessm ommended g | If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type | | | | | |
| Material | : Chemical-res | istant 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: | | | | | |
| Skin and body protection Hygiene measures | Skin should b If exposure to eye flushing s ing place. When using c | Skin should be washed after contact. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work- | | | | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

| Appearance | : Amorphous powder |
|------------------------------|---------------------|
| Colour | : white |
| Odour | : No data available |
| Odour Threshold | : No data available |
| рН | : 7.2 |
| Melting point/freezing point | : No data available |



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| | | | |
| Initial range | boiling point and boiling | : No data avai | lable |
| Flash | point | : No data avai | lable |
| Evapo | pration rate | : No data avai | lable |
| Flamr | nability (solid, gas) | : May form exp dling or other | blosive dust-air mixture during processing, har r means. |
| Flamn | nability (liquids) | : No data avai | lable |
| | r explosion limit / Upper ability limit | : No data avai | lable |
| | r explosion limit / Lower ability limit | : No data avai | lable |
| Vapou | ur pressure | : No data avai | lable |
| Relati | ve vapour density | : No data avai | lable |
| Relati | ve density | : No data avai | lable |
| Densi | ty | : 1 g/cm ³ | |
| | ility(ies) ater solubility | : No data avai | lable |
| | on coefficient: n- ol/water | : No data avai | lable |
| | gnition temperature | : No data avai | lable |
| Decor | mposition temperature | : No data avai | lable |
| Viscos Vis | sity scosity, kinematic | : No data avai | lable |
| Explo | sive properties | : Not explosive | 9 |
| Oxidiz | zing properties | : The substand | ce or mixture is not classified as oxidizing. |
| Molec | ular weight | : No data avai | lable |
| | le characteristics le size | : No data avai | lable |
| . STABI | LITY AND REACTIVITY | | |
| React Chem | ivity ical stability | | d as a reactivity hazard. normal conditions. |



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| Possi tions | bility of hazardous read | dling or othe | plosive dust-air mixture during processing, han r means. th strong oxidizing agents. |
| Incom | tions to avoid patible materials dous decomposition cts | : Heat, flames Avoid dust fo : Oxidizing ago | and sparks. prmation. |
| 1. TOXIC | OLOGICAL INFORMA | ATION | |
| Inform expos | nation on likely routes o sure | of : Inhalation Skin contact Ingestion Eye contact | |
| | e toxicity assified based on avai | lable information. | |
| Com | oonents: | | |
| Sucro Acute | ose: oral toxicity | : LD50 (Rat): 2 | 9,700 mg/kg |
| - | corrosion/irritation assified based on avai | lable information. | |
| <u>Com</u> | oonents: | | |
| Inflixi Rema | | : No data availa | able |
| Not cl | us eye damage/eye ir assified based on avai ponents: | | |
| Inflixi Rema | mab: | : No data availa | able |
| Resp | iratory or skin sensiti | sation | |
| Not cl | sensitisation assified based on avai | lable information. | |
| Not cl | iratory sensitisation assified based on avai | lable information. | |
| | cell mutagenicity assified based on avai | | |



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| | | | | |
| Com | ponents: | | | |
| Sucr | ose: | | | |
| Geno | otoxicity in vitro | : | Test Type: In viti Result: negative | o mammalian cell gene mutation test |
| Inflix | kimab: | | | |
| Geno | otoxicity in vitro | : | | erial reverse mutation assay (AMES) Fest Guideline 471 |
| | | | | mosomal aberration nan lymphoblastoid cells |
| Geno | otoxicity in vivo | : | Species: Mouse | nucleus test Fest Guideline 474 |
| | n cell mutagenicity - essment | : | Weight of eviden cell mutagen. | ce does not support classification as a germ |
| Carc | inogenicity | | | |
| Not o | classified based on avail | able | information. | |
| • | roductive toxicity classified based on avail | able | information. | |
| <u>Com</u> | ponents: | | | |
| Inflix | kimab: | | | |
| Effec | cts on fertility | : | Fertility: NOAEL: | ity e: Intravenous injection 40 mg/kg body weight on data from similar materials |
| Effect | ts on foetal develop- | : | Species: Mouse, Application Rout Duration of Singl General Toxicity Teratogenicity: N Developmental T Embryo-foetal to | yo-foetal development female e: Intravenous injection e Treatment: 6 - 12 d Maternal: NOAEL: 40 mg/kg body weight IOAEL F1: 40 mg/kg body weight oxicity: NOAEL F1: 40 xicity: NOAEL: 40 mg/kg body weight on data from similar materials |

STOT - single exposure

Not classified based on available information.

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| | | | | | |
| | стот | - repeated exposure | | | |
| | | assified based on availa | ble | information. | |
| | Repea | ted dose toxicity | | | |
| | <u>Comp</u> | onents: | | | |
| | Inflixir | nab: | | | |
| | Specie | | : | Mouse | |
| | NOAE Applica | L ation Route | : | 40 mg/kg Intravenous | |
| | Expos | ure time | : | 6 Months | |
| | Numbe | er of exposures | : | daily | |
| | Aspira | ation toxicity | | | |
| | Not cla | assified based on availa | ble | information. | |
| | Exper | ience with human exp | osi | ure | |
| | <u>Comp</u> | onents: | | | |
| | Inflixir | nab: | | | |
| | Inhalat | lion | : | Symptoms: Naus Fatigue, Headacl | ea, Vomiting, Abdominal pain, Diarrhoea, |
| 12 | | | | r aliguo, riodado | |
| 12. | ECOLU | | N | | |
| | Ecoto | xicity | | | |
| | Comp | onents: | | | |
| | Inflixir | nab: | | | |
| | Ecoto | xicology Assessment | | | |
| | Acute | aquatic toxicity | : | No data available | 9 |
| | Chroni | c aquatic toxicity | : | No data available |) |

SDS Number:

Persistence and degradability

No data available

Bioaccumulative potential

Components:

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

Mobility in soil No data available



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| No da | r adverse effects ata available DSAL CONSIDERATION | IS | | |
| | | | | |
| - | osal methods e from residues | : | | e of waste into sewer. |
| Conta | aminated packaging | : | Empty contained dling site for re | accordance with local regulations. ers should be taken to an approved waste han ecycling or disposal. e specified: Dispose of as unused product. |
| 4. TRAN | SPORT INFORMATION | | | |
| Interr | national Regulations | | | |
| Prope Class Subsi Packi Label Envire | umber er shipping name idiary risk ng group s onmentally hazardous | | Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no | |
| Class Subsi Packi Label Packi aircra Packi | D No. er shipping name idiary risk ng group s ng instruction (cargo | | Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable | |
| UN nu Prope Class Subsi Packi Label EmS | diary risk ng group s | | Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable | |

Not applicable for product as supplied.

Special precautions for user

Not applicable



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15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

| Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances |
|--|
| Hazardous to Health |

| Hazardous substances that must be registered | : | Not applicable |
|--|---|----------------|
|--|---|----------------|

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

| Hazardous substances approved for use | : | Not applicable |
|---------------------------------------|---|----------------|
| Prohibited substances | : | Not applicable |
| Restricted substances | : | Not applicable |

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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/ |
| Date format | : | yyyy/mm/dd |
| Full text of other abbreviatio | ns | |
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |



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| ID OEL | |
|--------|--|
| | |

: Indonesia. Occupational Exposure Limits

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 - 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.

ID / EN