

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Infliximab Formulation - (OGN)

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	06.04.2024	9883011-00007	Date of first issue: 19.10.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Infliximab Formulation - (OGN)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person
responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Infliximab	170277-31-3		>= 10 - < 20

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- Protection of first-aiders : No special precautions are necessary for first aid responders.
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Contact with dust can cause mechanical irritation or drying of

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the skin.
Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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

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cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

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Specific use(s) : No data available
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dusts non-specific 4 mg/m³
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)
Basis: IE OEL

10 mg/m³
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)
Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	OELV - 8 hrs (TWA)	10 mg/m ³	IE OEL
		OELV - 15 min (STEL)	20 mg/m ³	IE OEL
Infliximab	170277-31-3	TWA	150 µg/m ³	Internal

8.2 Exposure controls

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

Eye/face protection : Wear the following personal protective equipment:
Safety goggles
Equipment should conform to I.S. EN 166

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.

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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-

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Filter type : Recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 143
: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	Amorphous powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	7.2
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available

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Relative density	:	No data available
Density	:	1 g/cm ³
Relative vapour density	:	No data available
Particle characteristics	:	
Particle size	:	No data available

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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10.4 Conditions to avoid

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

Materials to avoid	:	Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

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 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:

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

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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Experience with human exposure

Components:

Infliximab:

Inhalation : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, Fatigue, Headache, Back pain

SECTION 12: Ecological information

12.1 Toxicity

Components:

Infliximab:

Ecotoxicology Assessment

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

- | | | |
|------------------------|---|--|
| Product | : | Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Do not dispose of waste into sewer. |
| 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

14.1 UN number or ID number

- | | | |
|------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

14.2 UN proper shipping name

- | | | |
|------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

14.3 Transport hazard class(es)

- | | | |
|------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

14.4 Packing group

- | | | |
|------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |

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IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

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Full text of H-Statements

Full text of other abbreviations

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

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/>

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

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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.

IE / EN