

REMICADE

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/15
1.87	2024/09/04	100000009639	Date of first issue: 2013/12/23

SECTION 1. IDENTIFICATION

Product name : REMICADE
Substance name : REMICADE 100mg lyophilized powder for IV infusion (Drug Product)
infliximab

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
Large Molecule Pharmaceutical intended for medical use.
Monoclonal antibody
Pharmacotherapeutic group: Immunosuppressive agents
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

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GHS label elements

Not a hazardous substance or mixture., Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
16.42 %

Other hazards

Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans.

Health Hazards, Risk Group 1

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization in susceptible persons.

This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.

Accidental injection may cause effects similar to those seen in clinical use and mentioned in the patient packaging insert.

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	>= 70 - < 90
Infliximab	170277-31-3	>= 10 - < 20

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with plenty of water.
If symptoms persist, call a physician.
Wash contaminated clothing before re-use.

In case of eye contact : Remove contact lenses.
Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Call a physician immediately.

If swallowed : Do NOT induce vomiting.

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If swallowed, rinse mouth with water (only if the person is conscious).
Drink plenty of water.
Call a physician immediately.

Most important symptoms and effects, both acute and delayed : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during firefighting : Risk of dust explosion.

Further information : Avoid dust formation.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Avoid direct contact with broken glass, plastic and other sharps.
Avoid breathing dust.
Evacuate personnel to safe areas.
Do not break, crush or spill this Finished Pharmaceutical Product.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and cleaning up : Small spills: Cover with absorbent soaked in 10% bleach solution. Allow 30 minutes contact time.
Large spills: Allow the dust/aerosol to settle for 30 minutes or use appropriate respiratory protection.
Cover the spilled material with absorbent towels/ pads.
Wet absorbent pad with 10% bleach solution. Allow 30 minutes contact time.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Clean up with a 10% bleach (5.25% sodium hypochlorite) solution, 1 part bleach, mixed with 9 parts water is

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recommended for cleaning of surfaces and equipment.
Clean spill location and adjacent surfaces thoroughly with ethanol or water with detergent.
Special consideration may need to be evaluated based on specific hazards.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Avoid dust formation.
- Advice on safe handling : Ensure all equipment is electrically grounded before beginning transfer operations.
Avoid formation of dust and aerosols.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.
Do not heat the product.
Use personal protective equipment as required.
Do not break, crush or spill this Finished Pharmaceutical Product.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.
Keep refrigerated.
- Recommended storage temperature : 36 - 46 °F / 2 - 8 °C

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1

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		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Infliximab	170277-31-3	PBOEL-HHC	2	J&J OEL/PBOEL HHC
Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 2.				
		TWA	0.028 mg/m ³	J&J OEL/PBOEL HHC
Further information: Notation RSEN: has the potential to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.				

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
The work area should be installed in accordance with the requirements of Biosafety level 1 (BSL1)

Personal protective equipment

Respiratory protection : Engineering controls should always be the primary method of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
No personal respiratory protective equipment normally required.

Hand protection
Remarks : Disposable gloves

Eye protection : Safety glasses

Skin and body protection : closed work clothing

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment.
Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
Remove gloves and wash hands when work with material is completed. Do not reuse gloves.
In some cases, wearing two pairs of gloves may be appropriate.
Contaminated work clothing should not be allowed out of the

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workplace.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder, (lyophilised), Vial
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	7.2
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No information available.
Self-ignition	:	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	:	No data available
Solubility(ies)		
<u>Water solubility</u>	:	No data available
<u>Solubility in other solvents</u>	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

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Explosive properties	:	No data available
Oxidizing properties	:	No data available
Sublimation point	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Heat, flames and sparks. Exposure to light.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation**Components:****Infliximab:**

Remarks	:	Large protein biotherapeutics in the dry or reconstituted (solution in buffer) forms are not expected to elicit skin corrosion/irritation, skin sensitization, or cause damage to/irritate the eyes.
Assessment	:	Single-dose acute toxicity studies were not performed. This product is a large protein biotherapeutic intended for injection. It is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure.

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Germ cell mutagenicity**Components:****Infliximab:**

Genotoxicity in vitro	:	Test Type: Chromosome aberration test in vitro Test system: Human lymphocytes Remarks: In vitro tests did not show mutagenic effects
Genotoxicity in vivo	:	Test Type: In vivo micronucleus test Result: In vivo tests did not show any chromosomal changes. Test Type: in vivo assay Result: In vivo tests did not show any chromosomal changes.
Germ cell mutagenicity - Assessment	:	Routine genotoxicity studies are not applicable to biotherapeutics as large proteins cannot diffuse into cells and interact with DNA or chromosomal material.

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

Species	:	Mouse
Exposure time	:	6 months
Dose	:	10 - 40 mg/kg
Remarks	:	Did not show carcinogenic effects in animal experiments.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity**Components:****Infliximab:**

Effects on fertility	:	Species: Mouse Dose: > 40 mg/kg Remarks: No adverse effects on sexual function and fertility.
Reproductive toxicity - Assessment	:	As maternal systemic exposure from handling is expected to be negligible and placental transfer of monoclonal antibodies in humans is very low during the period of organogenesis (1st trimester), embryo/fetal harm from worker exposure is considered unlikely.

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STOT - single exposure**Product:**

Remarks : Even though this does not meet GHS classification, inhalation of aerosol/dust from an acute exposure or significant overexposure may cause autoantibody formation or allergies.

STOT - repeated exposure

No data available

Repeated dose toxicity**Components:****Infliximab:**

Species : Mouse
: 10 - 40 mg/kg
Exposure time : 6 months
Remarks : No adverse effect has been observed in chronic toxicity tests.

Repeated dose toxicity - Assessment : Single-dose acute toxicity studies were not performed. This product is a large protein biotherapeutic intended for injection. It is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure.

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Toxicity to fish :
Remarks: No data available

Toxicity to daphnia and other :

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aquatic invertebrates Remarks: No data available

Toxicity to algae/aquatic plants :
Remarks: No data available

Components:

Infliximab:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Persistence and degradability

Product:

Biodegradability : Remarks: No data available

Components:

Infliximab:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

Components:

Infliximab:

Bioaccumulation : Remarks: No data available

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

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 : In accordance with National, Federal, State and Local regulations.
Decontaminate all waste (i.e. steam sterilization/autoclaving, chemical disinfection) before disposal or ensure incineration of medical waste as a proper disposal route

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.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

SARA 313

: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations**Massachusetts Right To Know**

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
SODIUM PHOSPHATE DIBASIC	7558-79-4

Pennsylvania Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
Infliximab	170277-31-3
SODIUM PHOSPHATE DIBASIC	7558-79-4

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New Jersey Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl Infliximab SODIUM PHOSPHATE DIBASIC	57-50-1 170277-31-3 7558-79-4
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New York City Hazardous Substances

SODIUM PHOSPHATE DIBASIC	7558-79-4
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California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

California List of Hazardous Substances

SODIUM PHOSPHATE DIBASIC	7558-79-4
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California Permissible Exposure Limits for Chemical Contaminants

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
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Other regulations

Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

Biosafety Regulations and Guidelines:

World Health Organization, Laboratory biosafety manual. - 4 th ed., ISBN 9789240011311, 2020, pp. 124.

OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030 and the OSHA Standard

Interpretation on Applicability of 1910.1030 to Establish Human Cell Lines;

U.S. Department of Health and Human Services Public Health Services, Biosafety in Microbiological and Biomedical Laboratories (BMBL) - 5th ed., HHS Publication No. (CDC) 21-1112

SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

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AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

Revision Date : 2024/09/04

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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