Version	Revision Date:	SDS Number:	Date of last issue: 2015/03/20
1.30	2015/04/21	100000009639	Date of first issue: 2013/12/23

SECTION 1. IDENTIFICATION

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

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560
US

Telephone : (609) 730-2000

Emergency telephone number : +32 14 60 24 44

E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
Large Molecule Pharmaceutical intended for medical use
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

Not a hazardous substance or mixture.

GHS Label element

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

Other hazards

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 respons. May cause sensitization of 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 accidently leaking, broken or crushed.
The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
16.42 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Infliximab	170277-31-3	>= 10 - < 20

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Artificial respiration and/or oxygen may be necessary.
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.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
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.

Unsuitable extinguishing media : Water spray jet

Specific hazards during fire-fighting : Heating can release hazardous gases.

Hazardous combustion products	:	No hazardous combustion products are known
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	:	Evacuate personnel to safe areas. 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 breathing dust. Avoid dust formation. 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	:	Clean up with soap and water or a solution containing at least 10% sodium hypochlorite (1 part sodium hypochlorite ("Bleach"), mixed with 9 parts water) is recommended for cleaning of surfaces and equipment. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations". Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal.Pick up and arrange without creating dust. Keep in properly labelled containers. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.

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. To avoid thermal decomposition, do not overheat. For personal protection see section 8. Avoid creating dust. Keep away from heat and sources of ignition. Avoid inhalation, ingestion and contact with skin and eyes. 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 locked up.

Recommended storage temperature : 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
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. This means that the OEL is estimated to be from 20 to 100 µg/m3			
		TWA	0.028 mg/m3	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.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.
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.

Hand protection

Remarks : No special precautions required.

Eye protection : No special precautions required.

Skin and body protection : No special precautions required.

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.

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.
Upper explosion limit	:	No data available
Lower explosion 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)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
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.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	Remarks: No data available

Components:

Infliximab

Acute oral toxicity	:	Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	Remarks: No data available

Skin corrosion/irritation

Product:

Remarks: No data available

Components:

Infliximab
Remarks: No data available

Serious eye damage/eye irritation

Product:

Remarks: No data available

Components:

Infliximab
Remarks: No data available

Respiratory or skin sensitisation

Product:

Remarks: No data available

Components:

Infliximab
Remarks: May cause sensitisation of susceptible persons.

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Remarks: No data available

Components:

Infliximab

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Species: 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.

Carcinogenicity

Product:

Remarks: No data available

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 identified as a carcinogen or potential carcinogen by OSHA.
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

Product:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Components:

Infliximab

Effects on fertility :
Species: Mouse
Dose: > 40 mg/kg

Remarks: No adverse effects on sexual function and fertility.

Effects on foetal development : Remarks: No data available

STOT - single exposure

Product:

Remarks: No data available

Components:

Infliximab

Remarks: No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Product:

Species: Mouse
10 - 40 mg/kg
Exposure time: 6 months

Remarks: No adverse effect has been observed in chronic toxicity tests.

Components:

Infliximab
Remarks: No data available

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

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

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International transport regulations

ADR
Not dangerous goods

RID
Not dangerous goods

DOT
Not dangerous goods

IATA
Not dangerous goods

IMDG
Not dangerous goods

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

Massachusetts Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	70 - 90 %

Pennsylvania Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	70 - 90 %
Infliximab	170277-31-3	10 - 20 %

New Jersey Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	70 - 90 %
Infliximab	170277-31-3	10 - 20 %

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.

Other regulations : According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
For professional users only.

This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

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

REACH : Not in compliance with the inventory

	:	alpha-D-Glucopyranoside, beta-D-fructofuranosyl
	:	Infliximab
CH INV	:	Not in compliance with the inventory
	:	alpha-D-Glucopyranoside, beta-D-fructofuranosyl
	:	Infliximab
TSCA	:	Not On TSCA Inventory
	:	Infliximab
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.
	:	Infliximab
AICS	:	Not in compliance with the inventory
	:	Infliximab
NZIoC	:	Not in compliance with the inventory
	:	Infliximab
ENCS	:	Not in compliance with the inventory
	:	alpha-D-Glucopyranoside, beta-D-fructofuranosyl
	:	Infliximab
ISHL	:	Not in compliance with the inventory
	:	alpha-D-Glucopyranoside, beta-D-fructofuranosyl
	:	Infliximab
KECI	:	Not in compliance with the inventory
	:	Infliximab
PICCS	:	Not in compliance with the inventory
	:	Infliximab
IECSC	:	Not in compliance with the inventory
	:	Infliximab

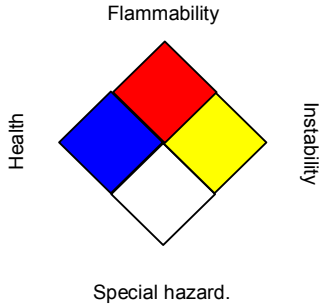
Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

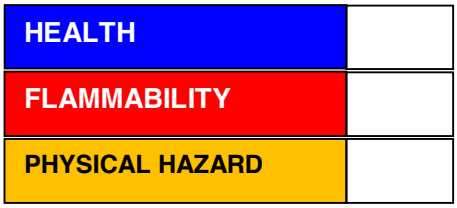
SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:



0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 2015/04/21

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	1,234,567.89

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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