SIMPONI

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SECTION 1. IDENTIFICATION

Product name : SIMPONI
Substance name : SIMPONI PFS prefilled syringe
CNTO 148
golimumab

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 not 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: 42 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Sucrose	57-50-1	>= 10 - < 20
GOLIMUMAB	Not Assigned	>= 5 - < 10

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.

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 : No information available.

Hazardous combustion products	:	No hazardous combustion products are known
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. Evacuate personnel to safe areas. Do not break, crush or spill this Finished Pharmaceutical Product.
Environmental precautions	:	Should not be released into the environment. Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers. Small spills: Gently cover the spill with an absorbent towel or pad. 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".

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Not applicable
Advice on safe handling	:	To avoid thermal decomposition, do not overheat. For personal protection see section 8. 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.
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
Sucrose	57-50-1	TWA	10 mg/m3	ACGIH
			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
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
GOLIMUMAB	Not Assigned	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.			

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 according to the concentration and amount of the dangerous substance

at the specific workplace.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solution, Prefilled syringe
Colour	:	clear, light yellow, opalescent
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	5 - 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	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available

Explosive properties	:	Not explosive (not expected to be explosive based on components)
Oxidizing properties	:	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. Exposure to light.
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

Components:

Sucrose

Acute oral toxicity	:	LD50 (Rat): 29,700 mg/kg
		LD50:

GOLIMUMAB

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)	:	(Monkey): 50 mg/kg Application Route: intravenous injection Remarks: No adverse effect has been observed in acute toxicity tests. (Monkey): 50 mg/kg Application Route: Subcutaneous; injection made in the back

or neck of animal
Remarks: No adverse effect has been observed in acute toxicity tests.

Skin corrosion/irritation

Product:
Remarks: No data available

Components:
GOLIMUMAB
Remarks: No data available

Serious eye damage/eye irritation

Product:
Remarks: No data available

Components:
GOLIMUMAB
Remarks: No data available

Respiratory or skin sensitisation

Product:
Remarks: No data available

Germ cell mutagenicity

Product:

Genotoxicity in vitro	:	Remarks: No data available
Genotoxicity in vivo	:	Remarks: No data available

Components:
GOLIMUMAB

Genotoxicity in vitro	:	Remarks: No data available
Genotoxicity in vivo	:	Remarks: No data available

Carcinogenicity

Product:
Remarks: No data available

Components:
GOLIMUMAB
Remarks: No data available

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:

GOLIMUMAB

Effects on fertility :
NOAEL: 50 mg/kg,
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.
No embryotoxic effects have been observed in animal tests.

Effects on foetal development : Remarks: Did not show teratogenic effects in animal experiments.

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.

Components:

GOLIMUMAB

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

Product:

Remarks: No data available

Repeated dose toxicity

Product:

Species: human

Application Route: intravenous injection
Dose: 0,1-10
Remarks: No adverse effect has been observed in chronic toxicity tests.

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
Toxicity to bacteria	:	Remarks: No data available

Components:

GOLIMUMAB

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:

GOLIMUMAB

Biodegradability	:	Remarks: No data available

Bioaccumulative potential

Product:

Bioaccumulation	:	Remarks: No data available

Components:

Sucrose

Partition coefficient: n-octanol/water	:	log Pow: -3.67

GOLIMUMAB

Bioaccumulation	:	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).
Additional ecological information	:	Should not be released into the environment.

Components:

GOLIMUMAB

Additional ecological information	:	There is no data available for this product. Should not be released into the environment.

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.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

Sucrose	57-50-1	10 - 20 %

Pennsylvania Right To Know

	Not Assigned	10 - 20 %
SORBITOL, L-BIO	50-70-4	10 - 20 %
Sucrose	57-50-1	10 - 20 %
GOLIMUMAB	Not Assigned	5 - 10 %

New Jersey Right To Know

	Not Assigned	10 - 20 %
SORBITOL, L-BIO	50-70-4	10 - 20 %
Sucrose	57-50-1	10 - 20 %
GOLIMUMAB	Not Assigned	5 - 10 %
	Not Assigned	1 - 5 %

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.

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

REACH : Not in compliance with the inventory

:

:

: SORBITOL, L-BIO

: Sucrose

:

: GOLIMUMAB

CH INV : Not in compliance with the inventory

:

:

: SORBITOL, L-BIO

: Sucrose

:

: GOLIMUMAB

TSCA : Not On TSCA Inventory

:

: GOLIMUMAB

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

:

: GOLIMUMAB

AICS : Not in compliance with the inventory

:

: GOLIMUMAB

NZIoC : Not in compliance with the inventory

	:	
	:	GOLIMUMAB
ENCS	:	Not in compliance with the inventory
	:	
	:	Sucrose
	:	
	:	GOLIMUMAB
ISHL	:	Not in compliance with the inventory
	:	
	:	Sucrose
	:	
	:	GOLIMUMAB
KECI	:	Not in compliance with the inventory
	:	
	:	GOLIMUMAB
PICCS	:	Not in compliance with the inventory
	:	
	:	GOLIMUMAB
IECSC	:	Not in compliance with the inventory
	:	
	:	GOLIMUMAB

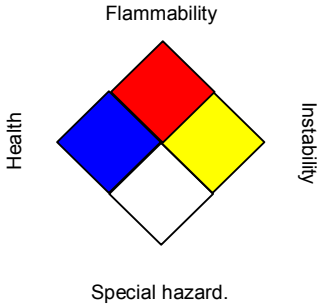
Inventories

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

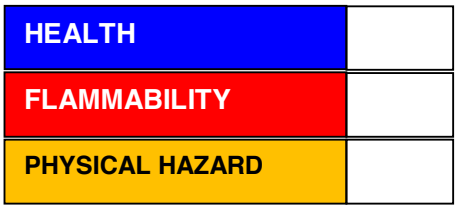
SECTION 16. OTHER INFORMATION

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	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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