Johnson & Johnson

SIMPONI

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1.94	2025/09/10	100000008610	Date of first issue: 2013/12/23

SECTION 1. IDENTIFICATION

Product name : SIMPONI
Substance name : SIMPONI PFS prefilled syringe (Drug Product)
CNTO 148
golimumab

Reference number : JNJ-54160301-AAA

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

Not a hazardous substance or mixture.

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: 42 %

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 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 accidently leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Components

Chemical name	CAS-No.	Concentration (% w/w)
INACTIVE	Not Assigned	>= 10 - < 20
golimumab	476181-74-5	>= 5 - < 10

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : If accidently injected (needle prick or through broken skin):
Stimulate bleeding for approximately 5 minutes.
Wash off immediately with soap and plenty of water.
Call a physician immediately.

If inhaled : If breathed in, move person into fresh air.
Rinse nose and mouth with salt water.
Call a physician immediately.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off immediately with soap and plenty of water.
If skin irritation persists, call a physician.
Consult a physician.
Process contaminated clothing and PPE's according to hospital procedures in accordance with applicable waste disposal regulations.

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. 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	:	No information available.
Hazardous combustion products	:	No hazardous combustion products are known
Further information	:	No information available.
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 splashes and spray formation. Evacuate personnel to safe areas. Avoid direct contact and significant aerosol exposure. 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	:	Small spills: Gently cover the spill with an absorbent towel or pad. Wet absorbent pad with 10% bleach solution. Allow 30 minutes contact time. Large spills: Allow the dust/aerosol to settle for 30 minutes or use appropriate respiratory protection. Dam up.

Soak up with inert absorbent material.
Add bleach (5.25% sodium hypochlorite) solution to a final liquid concentration of 10% (1 part bleach, mixed with 9 parts liquid) to absorbent materials. Allow 30 minute 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 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 : Not applicable

Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
Avoid splashes.
Avoid formation of aerosol.
To avoid thermal decomposition, do not overheat.
Avoid inhalation, ingestion and contact with skin and eyes.
Use personal protective equipment as required.

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
INACTIVE	Not Assigned		10 mg/m3	ACGIH
golimumab	476181-74-5	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

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 : 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 : 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.
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 workplace.

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.
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)

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:

INACTIVE:

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

Components:

golimumab:

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.

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

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

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 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

Product:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Components:

golimumab:

Effects on fertility : General Toxicity - Parent: 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.

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.

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 : No data available

STOT - repeated exposure

Product:

Remarks : No data available

Components:

golimumab:

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.

Components:

golimumab:

Remarks : No data available

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

Product:

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

INACTIVE:

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:

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

Components:

golimumab:

Additional ecological information : No data available

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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

histidine	71-00-1
SORBITOL, L-BIO	50-70-4
INACTIVE	Not Assigned
golimumab	476181-74-5

New Jersey Right To Know

histidine	71-00-1
SORBITOL, L-BIO	50-70-4
INACTIVE	Not Assigned
golimumab	476181-74-5
sorbitan monooleate, ethoxylated	9005-65-6

New York City Hazardous Substances

No components listed on the New York City Hazardous Substances List

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

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

Restricted to professional users.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	US. ACGIH Threshold Limit Values
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC

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 : 2025/09/10

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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