

SIMPONI ARIA

Version	Revision Date:	SDS Number:	Date of last issue:
1.30	2015/04/21	100000009560	2015/03/20
			Date of first issue: 2013/12/23

SECTION 1. IDENTIFICATION

Product name : SIMPONI ARIA
Substance name : SIMPONI ARIA
CNTO 148 antibody
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

Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. 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.

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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 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 accidentally leaking, broken or crushed.

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
97.63 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Sorbitol	50-70-4	>= 70 - < 90
GOLIMUMAB	Not Assigned	>= 20 - < 30

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 immediately 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 con- scious). 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 : Carbon dioxide (CO₂)

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Sand
Foam
Dry powder
Water mist
Aqueous film forming foam (AFFF).

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.
Avoid inhalation, ingestion and contact with skin and eyes.
For personal protection see section 8.
Do not break, crush or spill this Finished Pharmaceutical Product.

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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

Storage period : 24 Months

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
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.

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solution, Vial

Colour : clear, to, opalescent
colourless, to, light yellow

pH : 5.5

Flash point : No data available

Vapour pressure : 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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : To avoid thermal decomposition, do not overheat.
Protect from frost.
Exposure to sunlight.

Incompatible materials : None known.

Hazardous decomposition products : None known.

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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:**Sorbitol**

Acute oral toxicity : LD50 (Rat): 15,900 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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

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:**Sorbitol**

Remarks: No data available

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Remarks: No data available

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Serious eye damage/eye irritation**Product:**

Remarks: No data available

Components:**Sorbitol**

Remarks: No data available

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Remarks: No data available

Respiratory or skin sensitisation**Product:**

Remarks: May cause sensitization by inhalation.

Components:**Sorbitol**

Remarks: No data available

Germ cell mutagenicity**Product:**

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Germ cell mutagenicity - Assessment : Animal testing did not show any mutagenic effects.

Components:**Sorbitol**

Genotoxicity in vitro : Remarks: No data available

Germ cell mutagenicity - Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

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Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity**Product:**

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

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Components:**Sorbitol**

Remarks: No data available

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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: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Teratogenicity - Assessment

:

Animal testing did not show any effects on foetal development.

Components:**Sorbitol**

Effects on fertility

:

Remarks: No data available

Effects on foetal development

:

Remarks: No data available

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

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acute exposure or significant overexposure may cause autoantibody formation or allergies.

Components:**Sorbitol**

Remarks: No data available

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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:****Sorbitol**

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

Toxicity to bacteria : Remarks: No data available

Components:**Sorbitol**

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

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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

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Persistence and degradability**Product:**

Biodegradability : Remarks: No data available

Components:**Sorbitol**

Biodegradability : Remarks: Expected to be biodegradable

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Biodegradability : Remarks: No data available

Bioaccumulative potential**Product:**

Bioaccumulation : Remarks: No data available

Components:**Sorbitol**

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected. No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -2.20

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Bioaccumulation : Remarks: No data available

Mobility in soil**Product:**

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Product:**

Environmental fate and pathways : Remarks: No data available

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 : There is no data available for this product.

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information

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).

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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 SOCM I 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

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

Pennsylvania Right To Know

Sorbitol	50-70-4	70 - 90 %
GOLIMUMAB	Not Assigned	20 - 30 %

New Jersey Right To Know

Sorbitol	50-70-4	70 - 90 %
GOLIMUMAB	Not Assigned	20 - 30 %
L-Histidine, monohydrochloride, monohydrate	5934-29-2	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
	:
	:
	: GOLIMUMAB
	: Sorbitol
	: L-Histidine, monohydrochloride, monohydrate
CH INV	: Not in compliance with the inventory
	:

SAFETY DATA SHEET

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:
: GOLIMUMAB
: Sorbitol
: L-Histidine, monohydrochloride, monohydrate

TSCA : Not On TSCA Inventory
: GOLIMUMAB
: L-Histidine, monohydrochloride, monohydrate

DSL : This product contains the following components that are not
on the Canadian DSL nor NDSL.
: GOLIMUMAB
: L-Histidine, monohydrochloride, monohydrate

AICS : Not in compliance with the inventory
: GOLIMUMAB

NZIoC : Not in compliance with the inventory
: GOLIMUMAB

ENCS : Not in compliance with the inventory
:
: GOLIMUMAB
: L-Histidine, monohydrochloride, monohydrate

ISHL : Not in compliance with the inventory
:
: GOLIMUMAB
: L-Histidine, monohydrochloride, monohydrate

KECI : Not in compliance with the inventory
: GOLIMUMAB
: L-Histidine, monohydrochloride, monohydrate

PICCS : Not in compliance with the inventory
: GOLIMUMAB

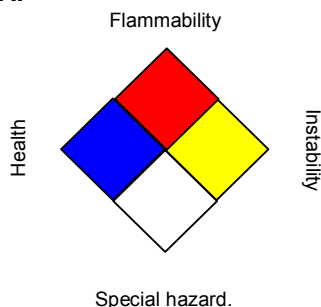
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IECSC : Not in compliance with the inventory
: GOLIMUMAB

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:**

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

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

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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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