Version	Revision Date:	SDS Number:	Date of last issue: 2015/03/20
1.37	2015/04/21	100000009229	Date of first issue: 2013/12/23

SECTION 1. IDENTIFICATION

Product name : STELARA
Substance name : CNTO 1275
ustekinumab
CNTO 1275 - 45mg vial/syringe
CNTO 1275 - 90mg vial/syringe
CNTO 1275 - 5mg/mL FVP (IV)(26mL fill volume in 30mL vial -130mg in vial) formulation

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: 9 %

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Ustekinumab	815610-63-0	>= < 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 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 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.

Specific hazards during firefighting : No information available.

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

for firefighters

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. 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 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. Protect against light.
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
Ustekinumab	815610-63-0	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.

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	:	Prefilled syringe, aqueous solution, Vial
Colour	:	colourless, light yellow
pH	:	ca. 6
Solubility(ies)		
Water solubility	:	soluble

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. Exposure to light.

Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Components:

Ustekinumab

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

Components:

Ustekinumab

Remarks: No data available

Serious eye damage/eye irritation

Components:

Ustekinumab

Remarks: No data available

Respiratory or skin sensitisation

Components:

Ustekinumab

Remarks: No data available

Germ cell mutagenicity

Components:

Ustekinumab

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

Carcinogenicity

Components:

Ustekinumab

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 : Sex: male
Dose: 45 mg/kg
Application Route: Subcutaneous; injection made in the back or neck of animal

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

Species: Mouse
Sex: female
Dose: 50 mg/kg
Application Route: Subcutaneous; injection made in the back or neck of animal

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

Effects on foetal development : Species: Monkey
Dose: 45 mg/kg
Number of exposures: weekly
Remarks: Did not show teratogenic effects in animal experiments.
Species: Monkey
Dose: 45 mg/kg
Number of exposures: twice weekly
Remarks: Did not show teratogenic effects in animal experiments.

Components:

Ustekinumab

Effects on fertility :

Remarks: No data available

Effects on foetal development : Remarks: No data available

Reproductive toxicity - : No information available.

Assessment

STOT - single exposure

Components:

Ustekinumab
Remarks: No data available

STOT - repeated exposure

Components:

Ustekinumab
Remarks: No data available

Repeated dose toxicity

Product:

Species: Monkey
45 mg/kg
Application Route: intravenous injection
Exposure time: 1 month
Number of exposures: weekly
Remarks: No adverse effect has been observed in chronic toxicity tests.

Species: Monkey
45 mg/kg
Application Route: Subcutaneous; injection made in the back or neck of animal
Exposure time: 6 months
Number of exposures: twice weekly
Remarks: No adverse effect has been observed in chronic toxicity tests.

Components:

Ustekinumab
Remarks: No data available

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ustekinumab

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

Components:

Ustekinumab

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

Ustekinumab

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 : No data available

Components:

Ustekinumab

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.

Massachusetts Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	5 - 10 %

Pennsylvania Right To Know

water	7732-18-5	70 - 90 %
Ustekinumab	815610-63-0	5 - 10 %
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	5 - 10 %

New Jersey Right To Know

water	7732-18-5	70 - 90 %
Ustekinumab	815610-63-0	5 - 10 %
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	5 - 10 %

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.
Restricted to professional users.

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

REACH : Not in compliance with the inventory

: Ustekinumab

: alpha-D-Glucopyranoside, beta-D-fructofuranosyl

: water

:

: histidine

:

CH INV : The formulation contains substances listed on the Swiss Inventory

: Ustekinumab

: alpha-D-Glucopyranoside, beta-D-fructofuranosyl

: water

:

: histidine

:

TSCA : Not On TSCA Inventory

: Ustekinumab

:

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

: Ustekinumab

:

AICS : Not in compliance with the inventory

: Ustekinumab

NZIoC : Not in compliance with the inventory

: Ustekinumab

ENCS : Not in compliance with the inventory

: Ustekinumab

: alpha-D-Glucopyranoside, beta-D-fructofuranosyl

: water

: histidine

:

ISHL : Not in compliance with the inventory

: Ustekinumab

: alpha-D-Glucopyranoside, beta-D-fructofuranosyl

: water

: histidine

:

KECI : Not in compliance with the inventory

: Ustekinumab

:

PICCS : Not in compliance with the inventory

: Ustekinumab

IECSC : Not in compliance with the inventory

: Ustekinumab

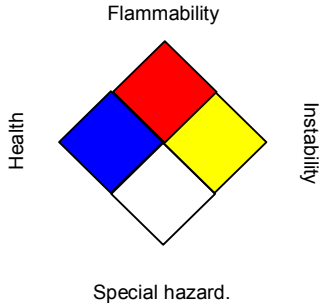
Inventories

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

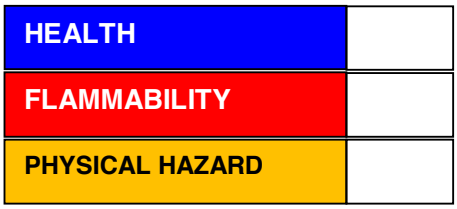
SECTION 16. OTHER INFORMATION

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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