

SAFETY DATA SHEET



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SECTION 1. IDENTIFICATION

Substance name : STELARA/STELARA ONE PRESS/FINLIUS
45 mg/0.5 mL solution in a single-dose prefilled syringe

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.
Monoclonal antibody
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

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. 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.

Immune system effects

High risk on infections

Long term or large scale exposure of this drug may lead to general immunosuppression.

Individuals who are at high risk (e.g. HIV-positive individuals, immunocompromised individuals) need to take precautions to minimize exposure.

Accidental injection may cause effects similar to those seen in clinical use and mentioned in the patient packaging insert.

No serious adverse effect would be expected for healthy individuals who inadvertently come into contact with the product and can be resolved without intervention.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ustekinumab	815610-63-0	$\geq 5 - < 10$
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	$\geq 5 - < 10$
polysorbate 80#	9005-65-6	< 0.1

Voluntarily-disclosed non-hazardous substance

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : If accidentally 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,

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- 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.
Product is digested in the GI tract and unlikely to be systemically absorbed in significant amounts.
- Most important symptoms and effects, both acute and delayed : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
sinusitis
nasopharyngitis
upper respiratory tract infection
Neurological disorders
Dizziness
Headache
Stomach/intestinal disorders
Diarrhoea
Nausea
Vomiting
Skin disorders
pruritis
Itching
Musculoskeletal disorders
Back pain
- 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 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.

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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 : No data available

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.

Recommended storage temperature : 36 - 46 °F / 2 - 8 °C

Further information on storage stability : Keep refrigerated., Do not freeze., Protect against light.

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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.				
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	TWA	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

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

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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	:	Prefilled syringe, Aqueous solution, Vial
Colour	:	colourless, light yellow
Odour	:	No data available
pH	:	ca. 6
Melting point/freezing point	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	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
Density	:	No data available
Solubility(ies)		
<u>Water solubility</u>	:	soluble
<u>Solubility in other solvents</u>	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
<u>Viscosity, kinematic</u>	:	No data available

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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****Components:****Ustekinumab:**

Acute oral toxicity	: Remarks: 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.
Acute inhalation toxicity	: Remarks: 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.
Acute dermal toxicity	: Remarks: 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.
Acute toxicity (other routes of administration)	: Remarks: 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. This product is intended for injection. This product is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure.

polysorbate 80:

Acute toxicity (other routes of administration)	: LD50 (Rat): 6,804 mg/kg Application Route: oral administration
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Skin corrosion/irritation**Components:****Ustekinumab:**

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.

Serious eye damage/eye irritation**Components:****Ustekinumab:**

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.

Respiratory or skin sensitisation**Components:****Ustekinumab:**

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 : No significant adverse effects were reported

Germ cell mutagenicity**Components:****Ustekinumab:**

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**Components:****Ustekinumab:**

Carcinogenicity - Assessment : Standard carcinogenicity bioassays are generally inappropriate for biotechnology derived pharmaceuticals.

This product has the potential to increase the risk of malignancy.

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.

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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

Components:

Ustekinumab:

Effects on fertility : Test Type: Fertility
Species: Monkey, male
Application Route: Subcutaneous; injection made in the back or neck of animal
General Toxicity - Parent: NOAEL: 45 mg/kg
GLP: yes
Remarks: No adverse effects on sexual function and fertility.

Test Type: Fertility
Species: Mouse, female
Application Route: Subcutaneous; injection made in the back or neck of animal
General Toxicity - Parent: NOAEL: 50 mg/kg
GLP: yes
Remarks: No adverse effects on sexual function and fertility.

Remarks: No effect on fertility endpoints was observed in non-human primates.

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Monkey, female
Application Route: intravenous injection
Frequency of Treatment: 1 days/week
General Toxicity Maternal: NOAEL: 45 mg/kg
Embryo-foetal toxicity: NOAEL: 45 mg/kg body weight
GLP: yes

Test Type: Fertility/early embryonic development
Species: Monkey, female
Application Route: Subcutaneous; injection made in the back or neck of animal
Frequency of Treatment: 2 days/week
General Toxicity Maternal: NOAEL: 45 mg/kg
Embryo-foetal toxicity: NOAEL: 45 mg/kg body weight
GLP: no

Test Type: Embryo-foetal development
Species: Monkey, female
Application Route: Subcutaneous; injection made in the back or neck of animal
Frequency of Treatment: 2 days/week
General Toxicity Maternal: NOAEL: 45 mg/kg
Embryo-foetal toxicity: NOAEL: 45 mg/kg body weight

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GLP: yes

Reproductive toxicity - Assessment : As an IgG1 monoclonal antibody, it may be transferred across the placenta.

Teratogenicity - Assessment : Did not show teratogenic effects in animal experiments.

No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

No effects on or via lactation

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:

Ustekinumab:

Remarks : Not applicable

STOT - repeated exposure

Components:

Ustekinumab:

Exposure routes : intravenous injection, Subcutaneous; injection made in the back or neck of animal

Target Organs : No specific target organs noted

Repeated dose toxicity

Components:

Ustekinumab:

Species : Monkey, male and female

NOAEL : 45 mg/kg

Application Route : intravenous injection

Exposure time : 1 month

Number of exposures : weekly

Dose : 9, 45 mg/kg

GLP : yes

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

Species : Monkey, male and female

NOAEL : 45 mg/kg

Application Route : Subcutaneous; injection made in the back or neck of animal

Exposure time : 6 months

Number of exposures : twice weekly

Dose : 22.5, 45 mg/kg

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

Repeated dose toxicity - Assessment : No significant adverse effects were reported

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

Components:

Ustekinumab:

Remarks : No immunotoxicity effects were observed.

Other health hazards

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/aquatic plants : Remarks: No data available

Persistence and degradability

Components:

Ustekinumab:

Biodegradability : Remarks: No data available

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Bioaccumulative potential

Components:

Ustekinumab:

Bioaccumulation : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

Product:

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.
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

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SECTION 15. REGULATORY INFORMATION**US State Regulations****Massachusetts Right To Know**

alpha-D-Glucopyranoside, beta-D-fructofuranosyl 57-50-1

Pennsylvania Right To Know

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

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

alpha-D-Glucopyranoside, beta-D-fructofuranosyl 57-50-1

Other regulations

Restricted to professional users.

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:

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

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

SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC : J&J OEL/PBOEL HHC
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1
Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
J&J OEL/PBOEL HHC / : PBOEL-HHC

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PBOEL-HHC
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour
workday during a 40-hour workweek
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average

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

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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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