SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
US OSHA Hazard Communication Standard (29 CFR 1910.1200)

Revision date 28-Mar-2025 **Revision Number** 1.1

1. Identification

Product identifier

Product Name SELARSDI™ (ustekinumab-aekn) Injection

Other means of identification

Product Code(s) FG01292

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical

Restrictions on use No information available

Details of the supplier of the safety data sheet

Manufacturer
Teva Pharmaceuticals USA, Inc.
400 Interpace Parkway, Building A,
Parsippany, NJ 07054, United States

E-mail SDS.TevaIL@teva.co.il

Emergency telephone number

Emergency Telephone United States/Canada/Puerto Rico: 1-800-424-9300 (Chemtrec) [24-hrs]
International: +1-703-741-5970 (Chemtrec) [24-hours]

2. Hazard(s) identification

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)
Not applicable.

Label elements

Hazard statements
This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Other information
No information available.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

The product contains no substances which at their given concentration, are considered to be hazardous to health.

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Rinse mouth.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
Effects of Exposure	No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.

Explosion data
Sensitivity to mechanical impact None.

Sensitivity to static discharge	None.
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

7. Handling and storage

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep at temperatures between 2 and 8 °C. Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	Appropriate eye/face protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.
Hand protection	Appropriate hand protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

Skin and body protection Appropriate skin and body protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

Respiratory protection Appropriate respiratory protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid
Appearance	No information available
Color	light yellow
Odor	No information available
Odor threshold	No information available

Property	**Values**	**Remarks • Method**
pH	No data available	None known
pH (as aqueous solution)		None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC content	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity .

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	482,926.80 mg/kg
ATEmix (dermal)	99,999.00 mg/kg
ATEmix (inhalation-gas)	99,999.00 ppm
ATEmix (inhalation-vapor)	99,999.00 mg/l
ATEmix (inhalation-dust/mist)	99,999.00 mg/l

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	There is no data for this product.
Other adverse effects	No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

DOT	Not regulated

15. Regulatory information

International Inventories

TSCA	Contact supplier for inventory compliance status.

Chemical name	CAS No.	Inventory Listing Status	Commercial Activity Designation
Water	7732-18-5	Present	Active
Sucrose	57-50-1	Present	Active
Methionine	63-68-3	Present	Active
ustekinumab-aekn	NA	-	Unknown *

*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL Contact supplier for inventory compliance status.
EINECS/ELINCS Contact supplier for inventory compliance status.
ENCS Contact supplier for inventory compliance status.
IECSC Contact supplier for inventory compliance status.
KECL Contact supplier for inventory compliance status.
PICCS Contact supplier for inventory compliance status.
AIIC Contact supplier for inventory compliance status.
NZIoC Contact supplier for inventory compliance status.

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AIIC - Australian Inventory of Industrial Chemicals
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Water 7732-18-5	-	-	X
Sucrose 57-50-1	-	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	**Health hazards** 0	**Flammability** 0	**Instability** 0	**Special hazards** -
HMIS	**Health hazards** 0	**Flammability** 0	**Physical hazards** 0	**Personal protection** X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend
SVHC: Substances of Very High Concern for Authorization:
PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances
vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances
STOT: Specific Target Organ Toxicity
ATE: Acute Toxicity Estimate
LC50: 50% Lethal Concentration
LD50: 50% Lethal Dose

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	Skin designation
+	Sensitizers		

Key literature references and sources for data used to compile the SDS
Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
Environmental Protection Agency
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
National Institute of Technology and Evaluation (NITE)
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine’s PubMed database (NLM PUBMED)
U.S. National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

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Disclaimer

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.

End of Safety Data Sheet