SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
US OSHA HCS 2024

Issuing Date 19-Dec-2024 **Revision date** 19-Dec-2024 **Revision Number** 1

1. Identification

Product identifier

Product Name Ustekinumab Injection

Other means of identification

Synonyms STARJEMZA

Other information Container Information: 1 mL prefilled syringes.
2 mL and 30 mL Glass vials.

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical
Prescription (Rx)

Restrictions on use Use only as directed

Details of the supplier of the safety data sheet

Supplier Address
Hikma Pharmaceuticals USA Inc
200 Connell Drive
Berkeley Heights, NJ 07922
1.908.673.1030

E-mail customerservice@hikma.com

Emergency telephone number

Emergency telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification of the substance or mixture
Not classified.

Hazards not otherwise classified (HNOC)
Not applicable.

Label elements

None

Hazard statements
Not classified.

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

No information available.

Other information
No information available.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Trade secret
Sucrose	57-50-1	5 - 10	*

*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, also under the eyelids.

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.

Unsuitable extinguishing media No information available.

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 Avoid contact with skin, eyes or clothing. Use PPE including respiratory protection and protective clothing.

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 Dispose of in accordance with federal, state and local regulations.

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. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and after work.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from light. Store at 2 - 8°C / 35.6 - 46.4°F. Store away from incompatible materials.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Sucrose 57-50-1	TWA: 10 mg/m^3	TWA: 15 mg/m^3 total dust TWA: 5 mg/m^3 respirable fraction (vacated) TWA: 15 mg/m^3 total dust (vacated) TWA: 5 mg/m^3 respirable fraction	TWA: 10 mg/m^3 total dust TWA: 5 mg/m^3 respirable dust

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection	Wear suitable gloves.
Skin and body protection	No special protective equipment required.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Colorless to Light yellow Clear liquid
Physical state	Liquid
Color	Colorless to light yellow
Odor (includes odor threshold)	Odorless

Property	Values	Remarks • Method
Melting point / freezing point		No data available
Boiling point (or initial boiling point or boiling range)		No data available
Flammability		No data available
Flammability Limit in Air		
Upper flammability or explosive limits		No data available
Lower flammability or explosive limits		No data available
Flash point		No data available
Autoignition temperature		No data available
Decomposition temperature		No data available
SADT (°C)		No data available
pH	5.7 - 6.3	
pH (as aqueous solution)		No data available
Kinematic viscosity		No data available
Dynamic viscosity		No data available
Solubility		No data available
Water solubility		No data available
Partition coefficient n-octanol/water (log value)		No data available
Vapor pressure (includes evaporation rate)		No data available
Evaporation rate		No data available
Density and/or relative density		No data available
Bulk density		No data available
Liquid Density		No data available
Relative vapor density		No data available
Particle characteristics		
Particle Size		No data available
Particle Size Distribution		No data available

Other information

Molecular weight	No information available
VOC content	No information available
Softening point	No information available

Information with regard to physical hazard classes

Explosives	
Explosive properties	No information available
Oxidizing properties	No information available

10. Stability and reactivity

Reactivity None under normal use conditions.

Chemical stability BAT2206 45 mg/0.5 mL and 130 mg/26 mL vials shelf life: 18 months when stored at 2-8℃ 45 mg/0.5 mL PFS with NSD and 90 mg/1 mL PFS with NSD shelf life: 36 months when stored at 2-8℃.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid Protect from light. High temperature.

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

Product Information .

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 No information available.

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose 57-50-1	= 29700 mg/kg (Rat)	-	-

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	No information available.
Other adverse effects	No information available.

13. Disposal considerations

Disposal 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
IATA	Not regulated
IMDG	Not regulated

15. Regulatory information

International Inventories

Contact supplier for inventory compliance status

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).

CAA (Clean Air Act)
This product does not contain any substances regulated as pollutants pursuant to Clean Air Act (CAA).

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
Sucrose 57-50-1	-	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention 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** -

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

Legend

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AIIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure

BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CMR	Carcinogen, Mutagen or Reproductive Toxicant
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
EmS	Emergency Schedule
ENCS	Existing and New Chemical Substances (Japan)
EPA	Environmental Protection Agency
GHS	Globally Harmonized System
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
ICAO	International Civil Aviation Organization
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organization for Standardization
KECI	Korean 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
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NTP	National Toxicology Program (United States)
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
OSHA	Occupational Safety and Health Administration of the US Department of Labor
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds

vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
Sen+	Sensitizer
Sk*	Skin designation
**	Hazard Designation

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)
Japan GHS Classification
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