OTULFI (ustekinumab-aauz) injection, for intravenous use

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 02/04/2025 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: OTULFI (ustekinumab-aauz) injection, for intravenous use

1.2. Intended Use of the Product

Pharmaceutical

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, Illinois 60047
USA
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
Email: NACommunications@fresenius-kabi.com

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
Domestic: 1-800-255-3924
International: +1-813-248-0585
Australia: 1-300-954-583
Brazil: 0-800-591-6042
China: 400-120-0751
India: 000-800-100-4086
Mexico: 800-099-0731

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified.

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	Aqua	(CAS-No.) 7732-18-5	89.7	Not classified.
Sucrose	.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl / Saccharose / Sugar / D-(+)-Sucrose / .beta.-D-Fructofuranosyl .alpha.-D-glucopyranoside / D-(+)-Saccharose / Sacarose / Sugar distillate	(CAS-No.) 57-50-1	5 - 10	Combustible Dust
Ustekinumab	ustekinumab	(CAS-No.) 815610-63-0	0.5	Skin Sens. 1B, H317
L-Histidine	Glyoxaline-5-alanine / Histidine / Histidine, L- / l-Histidine / L-(-) Histidine	(CAS-No.) 71-00-1	0.177	Combustible Dust

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives	Polyoxyethylene sorbitan monooleate / Sorbitan monooleate, ethoxylated / Sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives, (Z)- / Polyoxyethylene (5) sorbitan monooleate / PEG-3 SORBITAN OLEATE / Polyoxyethylene (20) sorbitan monooleate / Polyethylene glycol sorbitan monooleate / PEG-20 SORBITAN OLEATE / PEG sorbitan oleate / Sorbitan monooleate, ethoxylated (1-6.5 moles ethoxylated) / POLYSORBATE 80 / POLYSORBATE 81 / PEG-40 SORBITAN OLEATE / PEG-6 SORBITAN OLEATE / TWEEN 80	(CAS-No.) 9005-65-6	0.04	Combustible Dust
L-Methionine	Methionine / (S)-2-Amino-4-(methylthio)butanoic acid / 2-Amino-4-(methylthio)butyric acid / 2-Amino-4-methylthiobutanoic acid / Butanoic acid, 2-amino-4-(methylthio)-, (S)- / Butyric acid, 2-amino-4-(methylthio)- / S-Methionine / L-(-)-Methionine / Methionine, L- / l-Methionine	(CAS-No.) 63-68-3	0.04	Combustible Dust
Disodium EDTA	Acetic acid, (ethylenedinitrilo)tetra-, disodium salt / Disodium dihydrogen ethylenediaminetetraacetate / Disodium edetate / Disodium ethylenediaminetetraacetate / Disodium sequestrene / Disodium versenate / Edetate disodium / EDTA, disodium / Endrate disodium / Ethylenediaminetetraacetate, disodium / Ethylenediaminetetraacetate, disodium salt / Ethylenediaminetetraacetic acid, disodium salt / Sequestrene sodium 2 / Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt / EDTA disodium salt / Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2) / Versene disodium salt / Disodium salt of ethylenediaminetetraacetic acid / Disodium dihydrogen (ethylenedinitrilo)tetraacetate / Disodium dihydrogen EDTA / Edetate disodium anhydrous	(CAS-No.) 139-33-3	0.0018	Acute Tox. 4 (Inhalation), H332 STOT RE 2, H373

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Wash affected area with soap and water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. Obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: May cause an allergic reaction in sensitive individuals.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO_2), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO_2). Nitrogen oxides. Sulfur oxides.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing (vapor, mist, spray). Do not get in eyes, on skin, or on clothing. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Contains substances that are combustible dusts. If dried and allowed to accumulate, may form combustible dust concentrations in air that could ignite and cause an explosion. Take appropriate precautions.

Precautions for Safe Handling: If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Protect from light.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 2 – 8 °C (36 – 46 °F)

7.3. Specific End Use(s)

Pharmaceutical.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Sucrose (57-50-1)		
USA ACGIH	ACGIH OEL TWA	10 mg/m³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL TWA	15 mg/m³ (total dust) 5 mg/m³ (respirable fraction)
USA NIOSH	NIOSH REL TWA	10 mg/m³ (total dust) 5 mg/m³ (respirable dust)
Alberta	OEL TWA	10 mg/m³
British Columbia	OEL TWA	10 mg/m³ (total dust) 3 mg/m³ (respirable fraction)
Manitoba	OEL TWA	10 mg/m³
New Brunswick	OEL TWA	10 mg/m³
Newfoundland & Labrador	OEL TWA	10 mg/m³
Nova Scotia	OEL TWA	10 mg/m³
Nunavut	OEL STEL	20 mg/m³
Nunavut	OEL TWA	10 mg/m³
Northwest Territories	OEL STEL	20 mg/m³
Northwest Territories	OEL TWA	10 mg/m³
Ontario	OEL TWAEV	10 mg/m³
Prince Edward Island	OEL TWA	10 mg/m³
Québec	VEMP OEL TWAEV	10 mg/m³
Saskatchewan	OEL STEL	20 mg/m³
Saskatchewan	OEL TWA	10 mg/m³
Yukon	OEL STEL	20 mg/m³
Yukon	OEL TWA	30 mppcf 10 mg/m³

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.

Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance	:	Colorless to light yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	5.7 – 6.3
Evaporation Rate	:	No data available
Melting Point	:	No data available
Freezing Point	:	No data available
Boiling Point	:	No data available
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	Not applicable
Lower Flammable Limit	:	No data available
Upper Flammable Limit	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20 °C	:	No data available
Relative Density	:	No data available
Specific Gravity	:	No data available
Solubility	:	Water: Soluble
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides (CO, CO_2). Nitrogen oxides. Sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal. Eye contact.

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

LD50 and LC50 Data: No additional information available

Skin Corrosion/Irritation: Not classified.

Eye Damage/Irritation: Not classified.

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Reproductive Toxicity: Not classified.

Specific Target Organ Toxicity (Single Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

L-Histidine (71-00-1)	
LD50 Oral Rat	> 15 g/kg (Source: NLM_CIP)
Sucrose (57-50-1)	
LD50 Oral Rat	29700 mg/kg (Source: NLM_CIP)
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)	
LD50 Oral Rat	37.605 g/kg
Water (7732-18-5)	
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)
Disodium EDTA (139-33-3)	
LD50 Oral Rat	3.7 g/kg
LC50 Inhalation Rat	1500 mg/m³
L-Methionine (63-68-3)	
LD50 Oral Rat	36 g/kg (Source: NLM_CIP)

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Disodium EDTA (139-33-3)	
LC50 Fish	320 mg/l (Exposure time: 96 h - Species: Poecilia reticulata [semi-static] Source: IUCLID)

12.2. Persistence and Degradability

OTULFI (ustekinumab-aauz) injection, for intravenous use	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

OTULFI (ustekinumab-aauz) injection, for intravenous use	
Bioaccumulative Potential	Not established.
Disodium EDTA (139-33-3)	
Partition coefficient n-octanol/water (Log Pow)	-4.3 at 25 °C (at pH 4.5)
L-Methionine (63-68-3)	
Partition coefficient n-octanol/water (Log Pow)	-1.87 at 30 °C

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Product contaminated with biological materials should preferably be incinerated.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

L-Histidine (71-00-1)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Sucrose (57-50-1)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Disodium EDTA (139-33-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

L-Methionine (63-68-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

Sucrose (57-50-1)
U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List

15.3. Canadian Regulations

L-Histidine (71-00-1)
Listed on the Canadian DSL (Domestic Substances List)

Sucrose (57-50-1)
Listed on the Canadian DSL (Domestic Substances List)

Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)
Listed on the Canadian DSL (Domestic Substances List)

Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

Disodium EDTA (139-33-3)
Listed on the Canadian DSL (Domestic Substances List)

L-Methionine (63-68-3)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 02/04/2025

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

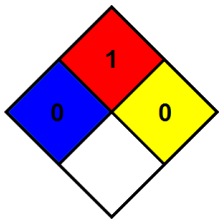
GHS Full Text Phrases:

H317	May cause an allergic skin reaction
H332	Harmful if inhaled
H373	May cause damage to organs through prolonged or repeated exposure

NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 1 Slight Hazard

Physical : 0 Minimal Hazard

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)
AU_WES: Australia WES
CHEMVIEW: ChemView (U.S. Environmental Protection Agency)
EC_RAR: European Commission Renewal Assessment Report
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports
ECHA_API: European Chemicals Agency API
ECHA_RAC: ECHA Committee for Risk Assessment
EFSA: European Food Safety Authority
EPA: U.S. Environmental Protection Agency
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)
EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)
EU_CLH: European Union Harmonised Classification and Labelling Proposal
EU_RAR: European Union Risk Assessment Report
FOOD_JOURN: Food Research Journal (1956)
IARC: The International Agency for Research on Cancer
IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles
IUCLID: International Uniform Chemical Information Database
JAPAN_GHS: Japan GHS Basis for Classification Data
JP_J-CHECK: Japan J-Check
KR_NIER: South Korea National Institute of Environmental Research Evaluations
NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
NLM_CIP: National Library of Medicine ChemID plus database
NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
NLM_PUBMED: National Library of Medicine PubMed database
NTP: National Toxicology Program
NZ_CCID: New Zealand Chemical Classification and Information Database
OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
WHO: World Health Organization

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)