

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: 05/31/2023 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Idacio (adalimumab-aacf) Injection For Subcutaneous Use

1.2. Intended Use of the Product

Idacio is indicated for Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis (adults only), and Plaque Psoriasis

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

Manufacturer

Fresenius Kabi USA, LLC Three Corporate Drive Lake Zurich, IL 60047 USA

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300 Health Issues Information: (800) 551-7176

http://www.fresenius-kabi.com/us/

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS

(800)255-3924 (North America) +1 (813)248-0585 (International)

USA Distributor

Fresenius Kabi USA, LLC Three Corporate Drive Lake Zurich, IL 60047 USA

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300 Health Issues Information: (800) 551-7176 http://www.fresenius-kabi.com/us/

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	water / AQUA	(CAS-No.) 7732-18-5	87.7	Not classified
Trehalose dihydrate	trehalose dihydrate / D-(+)-Trehalose dihydrate / Trehalose, dihydrate / .alphaD-Glucopyranosyl .alphaD-glucopyranoside dihydrate / .alphaD-Glucopyranoside, .alphaD-glucopyranosyl, dihydrate	(CAS-No.) 6138-23-4	6.85	Combustible Dust
Adalimumab-aacf	Immunoglobulin G1, anti-(human tumor necrosis factor) (human monoclonal D2E7 heavy chain), disulfide with human monoclonal D2E7 light chain, dimer / adalimumab	(CAS-No.) 331731-18-1	5	Not classified
Sodium chloride	Salt / SEA SALT / Sodium salt of hydrochloric acid / SODIUM CHLORIDE / Sodium chloride (NaCl) / Sea salt	(CAS-No.) 7647-14-5	0.29	Not classified

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Sorbitan, mono-(9Z)-9- octadecenoate, poly(oxy- 1,2-ethanediyl) derivatives	Sorbitan monooleate, ethoxylated (1-6.5 moles ethoxylated) / POLYSORBATE 80 / POLYSORBATE 81 / PEG-6 sorbitan oleate / PEG-40 sorbitan oleate / PEG-20 sorbitan oleate / PEG-40 SORBITAN OLEATE / PEG-6 SORBITAN OLEATE / PEG-6 SORBITAN OLEATE / PEG-9 Sorbitan oleate / PEG-20 SORBITAN OLEATE / Polyethylene glycol sorbitan monooleate / Polyoxyethylene (20) sorbitan monooleate / Polyoxyethylene (5) sorbitan monooleate / Polyoxyethylene (5) sorbitan monooleate / Sorbitan mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives, (Z)- / Sorbitan monooleate, ethoxylated / Polysorbate 80 / Polyoxyethylene sorbitan monooleate	(CAS-No.) 9005-65-6	0.1	Not classified
Acetic acid	ACETIC ACID / Acetic acid solution / Vinegar acid / Ethylic acid / Ethanoic acid / Acetic acid, glacial / Acetic acid %	(CAS-No.) 64-19-7	0.06	Flam. Liq. 3, H226 Met. Corr. 1, H290 Acute Tox. 4 (Inhalation:vapor), H332 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of H-statements: see section 16

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). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. **Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

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: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes. **Ingestion:** Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

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: Use extinguishing media suitable for surrounding type of fire.

Unsuitable Extinguishing Media: None known.

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.

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^{*}Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

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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, CO₂).

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 prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). 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. 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: Materials used during injections may be biologically contaminated with pathogenic organisms. Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents.

Precautions for Safe Handling: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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.

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

Storage Temperature: 2-8 °C (36-46 °F). Do not freeze. Can be stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 28 days.

7.3. Specific End Use(s)

Idacio is indicated for Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis (adults only), and Plaque Psoriasis

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.

Acetic acid (64-19-7)		
USA ACGIH	ACGIH OEL TWA [ppm]	10 ppm

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USA ACGIH	ACGIH OEL STEL [ppm]	ccording To The Hazardous Products Regulation (February 11, 2015). 15 ppm
USA OSHA	OSHA PEL (TWA) [1]	25 mg/m³
USA OSHA	OSHA PEL (TWA) [1] OSHA PEL (TWA) [2]	
	, , , , , ,	10 ppm
USA NIOSH	NIOSH REL (TWA)	25 mg/m³
USA NIOSH	NIOSH REL TWA [ppm]	10 ppm
USA NIOSH	NIOSH REL (STEL)	37 mg/m³
USA NIOSH	NIOSH REL STEL [ppm]	15 ppm
USA IDLH	IDLH [ppm] OEL STEL	50 ppm
Alberta		37 mg/m³
Alberta	OEL STEL [ppm]	15 ppm
Alberta	OEL TWA	25 mg/m³
Alberta	OEL TWA [ppm]	10 ppm
British Columbia	OEL STEL [ppm]	15 ppm
British Columbia	OEL TWA [ppm]	10 ppm
Manitoba	OEL STEL [ppm]	15 ppm
Manitoba	OEL TWA [ppm]	10 ppm
New Brunswick	OEL STEL	37 mg/m ³
New Brunswick	OEL STEL [ppm]	15 ppm
New Brunswick	OEL TWA	25 mg/m³
New Brunswick	OEL TWA [ppm]	10 ppm
Newfoundland & Labrador	OEL STEL [ppm]	15 ppm
Newfoundland & Labrador	OEL TWA [ppm]	10 ppm
Nova Scotia	OEL STEL [ppm]	15 ppm
Nova Scotia	OEL TWA [ppm]	10 ppm
Nunavut	OEL STEL [ppm]	15 ppm
Nunavut	OEL TWA [ppm]	10 ppm
Northwest Territories	OEL STEL [ppm]	15 ppm
Northwest Territories	OEL TWA [ppm]	10 ppm
Ontario	OEL STEL [ppm]	15 ppm
Ontario	OEL TWA [ppm]	10 ppm
Prince Edward Island	OEL STEL [ppm]	15 ppm
Prince Edward Island	OEL TWA [ppm]	10 ppm
Québec	VECD (OEL STEL)	37 mg/m ³
Québec	VECD (OEL STEL) [ppm]	15 ppm
Québec	VEMP (OEL TWA)	25 mg/m ³
Québec	VEMP (OEL TWA) [ppm]	10 ppm
Saskatchewan	OEL STEL [ppm]	15 ppm
Saskatchewan	OEL TWA [ppm]	10 ppm
Yukon	OEL STEL	43 mg/m ³
Yukon	OEL STEL [ppm]	25 ppm
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Yukon	OEL TWA	25 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 or glasses.







Materials for Protective Clothing: Chemically resistant materials and fabrics. **Hand Protection:** Wear protective gloves.

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Eve and Face Protection: Chemical safety goggles or safety glasses with side shields.

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.

No data available

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: LiquidAppearance: Not specifiedOdor: Not specifiedOdor Threshold: No data available

pH : 5.2

Evaporation Rate No data available **Melting Point** No data available **Freezing Point** 0 °C (32 °F) **Boiling Point** 100 °C (212 °F) **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 No data available Partition Coefficient: N-Octanol/Water No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Viscosity

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, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

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

pH: 5.2

Eye Damage/Irritation: Not classified

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pH: 5.2

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:** Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. Chronic Symptoms: None expected under normal conditions of use.

Potential Adverse human health effects and symptoms: Based on available data, the classification criteria are not met.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

LD30 and LC30 Data.		
Acetic acid (64-19-7)		
LD50 Oral Rat	3310 mg/kg	
LC50 Inhalation Rat	11.4 mg/l/4h	
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)		
LD50 Oral Rat	37.605 g/kg	
Sodium chloride (7647-14-5)		
LD50 Oral Rat	3550 mg/kg (Species: Wistar)	
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)	
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h)	

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

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Acetic acid (64-19-7)	
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-
	through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

12.2. Persistence and Degradability

Idacio (adalimumab-aacf) Injection For Subcutaneous Use	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

12.3. Dioaceamaiative i occitiai		
Idacio (adalimumab-aacf) Injection For Subcutaneous Use		
Bioaccumulative Potential	Not established.	
Acetic acid (64-19-7)		
Partition coefficient n-octanol/water (Log Pow)	-0.17 at 25 °C (at pH 7)	
Sodium chloride (7647-14-5)		
BCF Fish 1	(no bioaccumulation)	

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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.

Sewage Disposal Recommendations: Do not dispose of waste into sewer.

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

13.1. O3 Federal Regulations		
Acetic acid (64-19-7)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active		
CERCLA RQ	5000 lb	
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).	
Sodium chloride (7647-14-5)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active		
Water (7732-18-5)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active		

15.2. US State Regulations

Acetic acid (64-19-7)

- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List
- U.S. Massachusetts Right To Know List
- U.S. Pennsylvania RTK (Right to Know) Environmental Hazard List

15.3. Canadian Regulations

Acetic acid (64-19-7)

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)

Sodium chloride (7647-14-5)

Listed on the Canadian DSL (Domestic Substances List)

Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

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

Date of Preparation or Latest

: 05/31/2023

Revision

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:

H226	Flammable liquid and vapor
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H332	Harmful if inhaled
H402	Harmful to aquatic life

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.

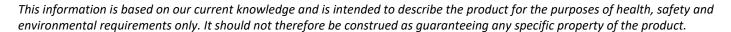
NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even

under fire conditions.

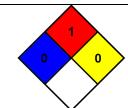
HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 1 Slight Hazard
Physical : 0 Minimal Hazard



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