

Product Name: Humira (R) (Adalimumab) Citrate Free
Issued: Mar-17-2017

abbvie
SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name: Humira (R) (Adalimumab) Citrate Free

List Number: 0554; 0243

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceuticals

1.3. Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

E-mail Address: AbbVie.SDS@abbvie.com

1.4. Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

Classification according to EU Directives 67/548/EEC or 1999/45/EC

2.2. Label elements

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

Chemical Name	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No
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Water 7732-18-5	80-90	Present		Not Hazardous*	No data available
Adalimumab L-02-3126	5-10	NA		Not Hazardous*	No data available
Mannitol 69-65-8	1-5	Present		Not Hazardous*	No data available
Polysorbate 80 9005-65-6	<1	NA		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms No signs and symptoms from occupational exposure are known. Clinical data suggests the following: headaches, coughing, rash, dizziness, nasal discharge, fever, gastrointestinal upset, leucopenia, variable cardiovascular system effects.

Medical Conditions Aggravated by Exposure None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: gastrointestinal system, cardiovascular system, lymphatic system, or hematopoietic system.

4.3. Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

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5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3. Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Disinfect with 10% (v/V) bleach solution. Dispose of material as directed in Section 13.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Water 7732-18-5	Not applicable	None
Adalimumab L-02-3126	200 mcg/m ³	None
Mannitol 69-65-8	Not applicable	None
Polysorbate 80 9005-65-6	Not applicable	None

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8.2. Exposure controls

Engineering Controls: No special provisions are required under normal conditions. When handling bulk formulation, use in a well-ventilated area.

Respiratory Protection: Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Clear/Colorless Solution

Odor: Odorless.

Odor Threshold: Not determined

pH: 4.7-5.7

Boiling Pt. @ 760 mm Hg (°C): Not determined

Melting/Freezing Point (°C): Not determined

Flash Point (°C): Not determined

Evaporation Rate at 20°C: Not determined

Flammability (Solid): Not determined

Lower Explosive Limit: Not determined

Upper Explosive Limit: Not determined

Vapor Pressure (mm Hg): Not determined

Vapor Density (Air = 1): Not determined

Density, g / mL: 1.01-1.05

Specific Gravity: Not determined

Solubility(ies): Freely soluble in: water.

Partition coefficient: Not determined

n-octanol/water

Autoignition Temp. (°C): Not determined

Decomposition temperature (°C): Not determined

Viscosity (centipoise): Not determined

Explosion Severity: Not determined

Oxidizer Properties: Not determined

9.2. Other information

Not determined

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SECTION 10: Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined

10.4. Conditions to avoid

Not determined

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below:

Chemical Name	Acute Test	Value	Units	Species
Mannitol 69-65-8	LD50 =	13,500-22,000	mg/kg	Mice Rats
Polysorbate 80 9005-65-6	LD50 =	25,000 - 36,570	mg/kg	Mice Rats

Acute Toxicity - Dermal: Not determined

Acute Toxicity - Inhalation: Not determined

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Adalimumab L-02-3126	ALD (iv) >	898	mg/kg	Rats Mice	None

Corrosivity: Not determined

Dermal Irritation: Active Ingredient(s): Produced little or no skin irritation in animals.

Eye irritation: Not determined

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Sensitization: Not determined

Toxicokinetics/Metabolism: Not determined

Target Organ Effects Data for component (s) given below:

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Adalimumab L-02-3126	Hematopoietic system Lymphatic system	Mice Liquid Monkeys	> 82.9	mg/kg/wk	Intravenous	Variable exposure periods
Mannitol 69-65-8	Eyes Kidney	Rats Mice	25,000	ppm	Oral Diet	Repeat dose study (ies).

Reproductive Effects Active Ingredient : Animal testing did not show any effects on fetal development
Animal testing did not show any effects on fertility

Chemical Name	Species	Dosage	Units	Route	Duration
Adalimumab L-02-3126	Monkeys	< 100	mg/kg/wk	Intravenous	Variable Treatment Regimens

Carcinogenicity Not determined

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Adalimumab L-02-3126	Negative	Negative	No Data.	No Data.

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

SECTION 12: Ecological information

12.1. Toxicity

Not determined

12.2. Persistence and degradability

Not determined

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined

12.5. Results of PBT and vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

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Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

SECTION 14: Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

14.1. UN number Not applicable

14.2. Proper shipping name: Not applicable

14.3. Hazard class: Not applicable

14.4. Packing group: Not applicable

14.5. Environmental hazard: Not applicable

14.6. Special provisions: Not applicable

14.7. Transport in bulk Not applicable

according to Annex II of
MARPOL 73/78 and the IBC

Code:

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Water 7732-18-5	Present	X	X	Not listed	X
Adalimumab L-02-3126	-	-	-	Not listed	-
Mannitol 69-65-8	Present	X	X	Not listed	X
Polysorbate 80 9005-65-6	-	X	X	Not listed	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Water 7732-18-5	-	-	X	X	Present	
Adalimumab L-02-3126	-	-	-	-	-	
Mannitol 69-65-8	Present	Present	X	X	Present	
Polysorbate 80 9005-65-6	Present	Present	X	X	Present	

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Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Weight-%	NTP:	IARC:	ACGIH:
Water	80-90	Not listed	Not listed	Not listed
Adalimumab	5-10	Not listed	Not listed	Not listed
Mannitol	1-5	Not listed	Not listed	Not listed
Polysorbate 80	<1	Not listed	Not listed	Not listed

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Water	80-90	No	Not applicable	Not applicable
Adalimumab	5-10	No	Not applicable	Not applicable
Mannitol	1-5	No	Not applicable	Not applicable
Polysorbate 80	<1	No	Not applicable	Not applicable

RCRA Status: Not determined

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class Exempt

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

SECTION 16: Other information

Document Authored By: Occupational and Environmental Toxicology

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