

Product Name: Humira (R) (Adalimumab)
Issued: Feb-25-2008



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
Pharmaceutical Products Group
100 Abbott Park Road
Abbott Park, IL 60064

Customer Service Telephone: 1-800-255-5162 (US and Canada only)

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

Product Name: Humira (R) (Adalimumab)

Synonyms: D2E7 Injection; Adalimumab; Humira (R) Pen; Humira (R) Single Dose Syringe, 40mg/0.8ml; Humira (R) Single Dose Autoinjector, 40mg/0.8ml; Humira Syringe; Humira 20 mg Pediatric Prefilled

List Number: 3799; 4339; 9374

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Water 7732-18-5	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Adalimumab L-02-3126	Proprietary	Not Listed	Not Listed	Not Applicable	30 mcg/m ³	None
Mannitol 69-65-8	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Mannitol 7647-14-5	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Sodium Citrate 68-04-2	Proprietary	15 mg/m ³ , total dust; 5 mg/m ³ , respirable fraction	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate	Not Applicable	Not Applicable	None
Sodium Phosphate Dihydrate, Dibasic 10028-24-7	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Polysorbate 80 9005-65-6	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None

Notes: OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

Abbott : Hazardous per OSHA criteria

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3. HAZARDS IDENTIFICATION

Emergency Overview:

Clear, colorless solution.
Odorless.
Refer to other MSDS sections for detailed information.

Routes of Exposure:

Oral: Not determined.
Dermal: Clinical Route
Inhalation: Not determined.

Hazard Information:

Ingestion Rating: Not determined.
Skin Absorption Rating: Not determined.
Inhalation Rating: Not determined.
Corrosiveness Rating: Not determined.
Skin Contact Rating: Not determined.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Not determined.
Target Organs: Cardiovascular System , Lymphatic System , Blood , Digestive System .

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Water	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Adalimumab	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Phosphate Dihydrate, Dibasic	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Polysorbate 80	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating: Not determined.

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 preexisting ailments in the following organs: gastrointestinal system, or hematopoietic system. cardiovascular system, lymphatic system.

4. 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.

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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.

5. FIRE FIGHTING MEASURES

Flammability:

Lower Explosive Limit: Not determined.

Autoignition Temp. (°C): Not determined.

Fire-Fighting Information:

Suitable Extinguishing Media: Use appropriate medium for the underlying cause of the fire.

Special Exposure Hazards: Avoid inhalation of combustion products.

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Disinfect any spills with a 10% bleach solution. Clean affected area with soap and water. Dispose of material as directed in Section 13.

Personal Precautions: Use personal protective equipment identified in Section 8.

Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Not determined.

Storage: Store according to label instructions.

Special Precautions: Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: Respiratory protection is not needed during normal product use.

Eyes: Eye protection not required during typical product use conditions. Wear eye protection appropriate to exposures when handling the product formulation.

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

Other PPE Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless solution.
Odor: Odorless.
Boiling Pt. @ 760 mm Hg (°C): Not determined.
Melting/Freezing Point (°C): Not determined.
Vapor Pressure (mm Hg) Not determined.
Bulk Density at 20°C: Not determined.
Solubility: Not determined.
Specific Gravity: Not determined.
pH: Not determined.
Viscosity (centipoise): Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Not determined.
Self-Heating Tendency: Not determined.
Materials to Avoid: Not determined.
Hazardous Decomposition Products: Not determined.
Hazardous Polymerization: Not determined.
Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Not determined. Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Mannitol	Proprietary	LD50 =	13,500-22,000	mg/kg	Mice Rats
Mannitol	Proprietary	LD50 >	4000	mg/kg	Rats Mice Rabbits
Sodium Phosphate Dihydrate, Dibasic	Proprietary	LD50 =	17,000	mg/kg	Rats
Polysorbate 80	Proprietary	LD50 =	25,000 - 36,570	mg/kg	Mice Rats

Acute Toxicity - Dermal: Not determined. Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Mannitol	Proprietary	LD50 >	10,000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined. Data for component (s) given below.

Ingredients	Percent	Test	Value	Units	Species
Mannitol	Proprietary	LC 50 >	42	mg/L	Rats

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

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Adalimumab	Proprietary	ALD (iv) >	898	mg/kg	Rats Mice	None.
Sodium Phosphate Dihydrate, Dibasic	Proprietary	LD Lo (ip) =	1000	mg/kg	Rats	None.

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Corrosivity: Not determined.

Dermal Irritation: Not determined. Active Ingredient : Produced little or no skin irritation in animals.

Eye Irritation: Not determined.

Sensitization: Not determined.

Target Organ Effects: Not determined. Active Ingredient : In clinical use target organ effects include: gastrointestinal tract, hematopoietic system, cardiovascular system, lymphatic system. Data for component (s) given below.

Ingredients	Percent	Target Organs:	Species	Dosage	Units	Route	Duration
Adalimumab	Proprietary	Hematopoietic system Lymphatic system	Mice Monkeys	> 82.9	mg/kg/wk	Intravenous	Variable exposure periods
Mannitol	Proprietary	Eyes Kidney	Rats Mice	25,000	ppm	Oral Diet	Repeat dose study (ies).

Reproductive Effects: Not determined. Active Ingredient : No effects were seen in an embryo-fetal perinatal study in monkeys.

Ingredients	Percent	Reproductive Effects	Species	Dosage	Units	Route	Duration
Adalimumab	Proprietary	No adverse effect.	Monkeys	< 100	mg/kg/wk	Intravenous	Variable Treatment Regimens

Carcinogenicity: Not determined.

Mutagenicity: Not determined. Active Ingredient : Negative in the Ames assay. Negative in the micronucleus test. Data for component (s) given below.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
Adalimumab	Proprietary	Negative	No Data.	Negative	No Data.

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

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

Biodegradation: Not determined.

General Notes: 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.

13. DISPOSAL CONSIDERATIONS

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13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

DOT/ADR:
Status: Not Regulated.

ICAO/IATA:
Status: Not Regulated.

IMDG:
Status: Not Regulated.

TDG (Canada):
Status: Not Regulated.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Water	Proprietary	No	Not Applicable	Not applicable
Adalimumab	Proprietary	No	Not Applicable	Not applicable
Mannitol	Proprietary	No	Not Applicable	Not applicable
Mannitol	Proprietary	No	Not Applicable	Not applicable
Sodium Citrate	Proprietary	No	Not Applicable	Not applicable
Sodium Phosphate Dihydrate, Dibasic	Proprietary	No	Not Applicable	Not applicable
Polysorbate 80	Proprietary	No	Not Applicable	Not applicable

SARA 311/312 Hazard Categories:

Immediate Health: No
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

TSCA Inventory Status: Exempt.

CERCLA Status: Not determined.

RCRA Status: Not determined.

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

EC HAZARD CLASSIFICATION:

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Category of Danger: Exempt.
Indication of danger: Exempt.
GHS Classification: Not determined.

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.
Canadian NDSL: Not determined.
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.

16. OTHER INFORMATION

Document Authored By: Global Occupational Toxicology (D-05TX)

Supersedes the MSDS dated: Jul-12-2006

Disclaimer:

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