

**Product Name:** Humira (ANZ)  
**Issued:** Sep-25-2014



## **SAFETY DATA SHEET**

### **Section 1. Identification of the substance/mixture and of the company/undertaking**

#### **1.1 Product Identifier**

**Product Name:** Humira (ANZ)  
**Synonyms:** Humira (R) Pen Autoinject; Humira (R) Pen; Humira Injection  
**Trade name:** Humira  
**List Number:** 3799; 4339

#### **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:** Manufactured for:  
AbbVie  
L1, 32-34 Lord St.  
Botany, NSW 2019  
Australia

**E-mail Address:** medinfoanz@abbvie.com

#### **1.4 Emergency telephone number**

**Emergency Telephone:** 1800 043 460 (AU)  
0800 900 030 (NZ)

### **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**

**Indication of danger:** Not classified

#### **2.2 Label elements**

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

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## Section 2. Hazards identification

### 2.3 Other hazards

Not determined

## Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Water 7732-18-5	85-95	Present		Not Hazardous*	No data available
Adalimumab	1-15	NA		Not Hazardous*	No data available
Mannitol 69-65-8	1-10	Present		Not Hazardous*	No data available
Sodium Chloride 7647-14-5	0-1	Present		Not Hazardous*	No data available
Sodium Phosphate Dihydrate, Dibasic 10028-24-7	0-1	NA		Not Hazardous*	No data available
Citric Acid 77-92-9	0-1	Present	Xi; R36/37/38	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	No data available
Polysorbate 80 9005-65-6	0.1-1	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

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#### **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, or hematopoietic system. cardiovascular system, lymphatic 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

#### **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.

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### 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:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
Water 7732-18-5	Not Applicable	None
Adalimumab	30 mcg/m <sup>3</sup>	None
Mannitol 69-65-8	Not Applicable	None
Sodium Chloride 7647-14-5	Not Applicable	None
Sodium Phosphate Dihydrate, Dibasic 10028-24-7	Not Applicable	None
Citric Acid 77-92-9	Not Applicable	None
Polysorbate 80 9005-65-6	Not Applicable	None

### 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.

<b>Product Name:</b>	<b>Humira (ANZ)</b>
<b>Issued:</b>	<b>Sep-25-2014</b>
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	4.7-5.7
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	Not determined.
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Density, g / mL:</b>	1.01-1.05
<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Freely soluble in: water.
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

## 9.2. Other information

Not determined

## **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

**Product Name:** Humira (ANZ)  
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**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
Sodium Chloride 7647-14-5	LD50 =	3550	mg/kg	Rats
Sodium Phosphate Dihydrate, Dibasic 10028-24-7	LD50 =	17,000	mg/kg	Rats
Citric Acid 77-92-9	LD50 >=	3000	mg/kg	Animals
Polysorbate 80 9005-65-6	LD50 =	25,000 - 36,570	mg/kg	Mice Rats

**Acute Toxicity - Dermal:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Sodium Chloride 7647-14-5	LD50 >	10,000	mg/kg	Rabbits

**Acute Toxicity - Inhalation:** Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Sodium Chloride 7647-14-5	LC 50 >	42	mg/L	Rats

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

Chemical Name	Test Type	Value	Units	Species	Comments
Adalimumab	ALD (iv) >	898	mg/kg	Rats Mice	None.
Sodium Phosphate Dihydrate, Dibasic 10028-24-7	LD Lo (ip) =	1000	mg/kg	Rats	None.

**Corrosivity:** Not determined.

**Dermal Irritation:** Active Ingredient : Produced little or no skin irritation in animals.

**Eye Irritation:** Not determined.

**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	Hematopoietic system Lymphatic system	Mice 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

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Chemical Name	Species	Dosage	Units	Route	Duration
Adalimumab	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	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

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Sodium Chloride 7647-14-5	0-1	1295	Fathead Minnow	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Sodium Chloride 7647-14-5	0-1	1661	Daphnia magna	48 Hours

### 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 or vPvB assessment

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

### 12.6. Other adverse effects

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

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**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 according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

**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	-	-	-	Not listed.	-
Mannitol 69-65-8	Present	X	X	Not listed.	X
Sodium Chloride 7647-14-5	Present	X	X	Not listed.	X
Sodium Phosphate Dihydrate, Dibasic 10028-24-7	-	-	-	Not listed.	X
Citric Acid 77-92-9	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	-	2-(4)-1220	X	X	Present	
Adalimumab	-	-	-	-	-	



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Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Mannitol 69-65-8	Present	Present	X	X	Present	
Sodium Chloride 7647-14-5	Present	-	X	X	Present	HSR002722
Sodium Phosphate Dihydrate, Dibasic 10028-24-7	-	-	X	X	-	HSR003588
Citric Acid 77-92-9	Present	-	X	X	Present	HSR003138
Polysorbate 80 9005-65-6	Present	Present	X	X	Present	

### 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	Percent	NTP:	IARC:	ACGIH:
Water	85-95	Not Listed	Not Listed	Not Listed
Adalimumab	1-15	Not Listed	Not Listed	Not Listed
Mannitol	1-10	Not Listed	Not Listed	Not Listed
Sodium Chloride	0-1	Not Listed	Not Listed	Not Listed
Sodium Phosphate Dihydrate, Dibasic	0-1	Not Listed	Not Listed	Not Listed
Citric Acid	0-1	Not Listed	Not Listed	Not Listed
Polysorbate 80	0.1-1	Not Listed	Not Listed	Not Listed

### SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Water	85-95	No	Not Applicable	Not applicable
Adalimumab	1-15	No	Not Applicable	Not applicable
Mannitol	1-10	No	Not Applicable	Not applicable
Sodium Chloride	0-1	No	Not Applicable	Not applicable
Sodium Phosphate Dihydrate, Dibasic	0-1	No	Not Applicable	Not applicable
Citric Acid	0-1	No	Not Applicable	Not applicable
Polysorbate 80	0.1-1	No	Not Applicable	Not applicable

**Immediate Health:** No

**Delayed Health:** No

**Fire:** No

**Sudden Pressure:** No

**Reactivity:** No

**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

**NFPA Rating:**

Health: 0

Fire: 0

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Reactivity: 0

**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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