

Product Name: Adalimumab
Issued: Oct-24-2016



SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Adalimumab

Synonyms: Adalimumab Bulk; Adalimumab Drug Substance; Adalimumab Bulk Drug Substance; D2E7 Bulk; Human THF Antibody Drug Substance; LU200134; LU 200134

List Number: M504

Drug Code Number: 83363; 74249; 70281; 74929; 87692; 61479; 13458; 58592; 83429; 57907; 64713; 13367; 81888; 87581

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

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

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

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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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 |
|--|----------|----------------------|--------------------|-----------------------------------|-------------------|
| Water 7732-18-5 | 90-95 | Present | | Not Hazardous* | No data available |
| Adalimumab | 1-10 | NA | | Not Hazardous* | No data available |
| Mannitol 69-65-8 | 1-5 | Present | | Not Hazardous* | No data available |
| SODIUM CHLORIDE 7647-14-5 | 0.1-1 | Present | | Not Hazardous* | No data available |
| Sodium Phosphate Dihydrate, Dibasic 10028-24-7 | 0.1-1 | NA | | Not Hazardous* | 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

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, gastrointestinal upset, nasal discharge, fever, leucopenia, variable cardiovascular system effects.

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

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

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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 | 200 mcg/m ³ | 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 |
| Polysorbate 80 9005-65-6 | Not applicable | None |

8.2. Exposure controls

Engineering Controls: Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Wear coveralls if splashing or contact may occur.

Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Colorless Liquid
Odor: Odorless.
Odor Threshold: Not determined
pH: 5.0-5.4
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

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Vapor Density (Air = 1): Not determined
Density, g / mL: 1.03
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 |
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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

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| SECTION 11: Toxicological information |
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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 |
|---------------|------------|-------|-------|---------|
|---------------|------------|-------|-------|---------|

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| | | | | |
|---|--------|-----------------|-------|-----------|
| Mannitol 69-65-8 | LD50 = | 13,500-22,000 | mg/kg | Mice Rats |
| Sodium Phosphate Dihydrate, Dibasic 10028-24-7 | LD50 = | 17,000 | mg/kg | 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 | 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: 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

| 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

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Data for component (s) given below:

| Chemical Name | Weight-% | LC 50 (mg/l) | Species | Duration |
|------------------------------|----------|--------------|----------------|----------|
| SODIUM CHLORIDE 7647-14-5 | 0.1-1 | 1295 | Fathead Minnow | 96 Hours |

| Chemical Name | Weight-% | 48h EC50 (daphnia - mg/l) (48HLCD) | Species | Duration |
|------------------------------|----------|---------------------------------------|---------------|----------|
| SODIUM CHLORIDE 7647-14-5 | 0.1-1 | 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 and 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.

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

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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 |
| 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 | - | - | - | - | - | |
| 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 |
| 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 | Weight-% | NTP: | IARC: | ACGIH: |
|-------------------------------------|----------|------------|------------|------------|
| Water | 90-95 | Not listed | Not listed | Not listed |
| Adalimumab | 1-10 | Not listed | Not listed | Not listed |
| Mannitol | 1-5 | Not listed | Not listed | Not listed |
| SODIUM CHLORIDE | 0.1-1 | Not listed | Not listed | Not listed |
| Sodium Phosphate Dihydrate, Dibasic | 0.1-1 | Not listed | Not listed | Not listed |
| Polysorbate 80 | 0.1-1 | Not listed | Not listed | Not listed |

SARA 313 Information

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| Chemical Name | Weight-% | SARA 313 Chemical: | CERCLA RQ/SARA EHS RQ (lbs): | SARA EHS TPQ (lbs): |
|-------------------------------------|----------|--------------------|------------------------------|---------------------|
| Water | 90-95 | No | Not applicable | Not applicable |
| Adalimumab | 1-10 | No | Not applicable | Not applicable |
| Mannitol | 1-5 | No | Not applicable | Not applicable |
| SODIUM CHLORIDE | 0.1-1 | No | Not applicable | Not applicable |
| Sodium Phosphate Dihydrate, Dibasic | 0.1-1 | 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 Not determined

NFPA Rating:
Health: 0
Fire: 0
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

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Supersedes the SDS dated: Aug-24-2011

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