



Revision Number: 10

# AMJEVITA™ Safety Data Sheet

Date Issued 17-Aug-2023

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERSTANDING

### 1.1 Product identifier

**Product Name:** AMJEVITA™  
**Common Name:** adalimumab-otto  
**Chemical Name:** anti-TNF alpha monoclonal antibody  
**Synonyms:** AMJEVITA™ (US), AMGEVITA® (EU), ABP 501

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

**Recommended Use:** Pharmaceutical  
**Uses advised against:** No information available

#### Manufacturer:

Amgen Inc.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799  
1-805-447-7233  
1-805-447-1000

#### Emergency Telephone Number:

Chemtrec  
NORTH AMERICA 1-800-424-9300,  
INTERNATIONAL 1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Emergency Overview

Pharmaceutical product intended for clinical and commercial manufacturing purposes only. Product contains adalimumab-otto, an active pharmaceutical ingredient for treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's Disease, ulcerative colitis, and plaque psoriasis. Dosage contents may pose a health hazard only if significant absorption occurs (e.g. inhalation after a major spill or leak). Avoid inhalation, skin contact, eye contact, and accidental ingestions. Does not meet GHS classification criteria and therefore is not classified

### 2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable) REGULATION (EC) No 1272/2008

Not classified

### 2.2 Label elements

Not classified

### 2.3 Other Hazards

No information available



# AMJEVITA™

## Safety Data Sheet

Revision Number: 10

Date Issued 17-Aug-2023

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

**Ingredients:** See below

**Chemical Name:** anti-TNF alpha monoclonal antibody

**CAS-No:** 1446410-95-2

Single-dose prefilled SureClick® autoinjector: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL formulated with glacial acetic acid, polysorbate 80, sodium hydroxide for pH adjustment, sucrose, and Water for Injection, USP, pH 5.2.

Single-dose prefilled glass syringe: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL, 20 mg/0.4 mL, 20 mg/0.2 mL, 10 mg/0.2 mL formulated with glacial acetic acid, polysorbate 80, sodium hydroxide for pH adjustment, sucrose and Water for Injection, USP, pH 5.2.

### 4. FIRST AID MEASURES

#### 4.1 Description of first-aid measures

**Eye Contact:** In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

**Inhalation:** Move to fresh air. If symptoms persist, call a physician.

**Ingestion:** If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

**Notes to Physician:** Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

#### 5.1 Extinguishing media

**Flammable Properties:** No information available.

**Extinguishing Media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

#### 5.2 Special hazards arising from the substance or mixture

**Hazardous Combustion Products:** No information available.

#### 5.3 Advice for firefighters

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.



Revision Number: 10

# AMJEVITA™

## Safety Data Sheet

Date Issued 17-Aug-2023

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

**Spill Procedures:**

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

### 7. HANDLING AND STORAGE

#### 7.1 Precautions for Safe Handling

**Handling and Storage:**

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.



Revision Number: 10

# AMJEVITA™

## Safety Data Sheet

Date Issued 17-Aug-2023

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

**Occupational Exposure Limit:** No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 30 µg/m<sup>3</sup> as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Adalimumab-otto has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound (20 µg/m<sup>3</sup> - 100 µg/m<sup>3</sup>).

**Engineering Controls:** Handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood. The choice of engineering controls should be dependent on the job activity, task, quantities handled, and physical state of material.

#### 8.2 Exposure controls

##### Personal Protective Equipment

**Eye/face Protection:** Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

**Skin Protection:** Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

**Respiratory Protection:** No respiratory protective equipment normally required. The choice or protection should be based on the job activity.

**Other:** Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

#### 8.3 Environmental exposure controls

**Environmental Exposure Controls** Avoid release to the environment.



# AMJEVITA™

## Safety Data Sheet

Revision Number: 10

Date Issued 17-Aug-2023

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear to colorless
<b>Physical State:</b>	Liquid
<b>Molecular Weight:</b>	105 kDa
<b>Odor:</b>	Not applicable
<b>Odor Threshold:</b>	Not applicable
<b>pH:</b>	5.2
<b>Melting point (°C) VALUE</b>	No information available
<b>Flash Point:</b>	Not applicable
<b>Evaporation Rate:</b>	Not applicable
<b>Lower explosive limit:</b>	Not applicable
<b>Upper explosive limit:</b>	Not applicable
<b>Vapor Pressure:</b>	Not applicable
<b>Vapor Density (air = 1):</b>	Not applicable
<b>Relative density:</b>	Not applicable
<b>Water Solubility:</b>	Not applicable
<b>Partition Coefficient (log Kow):</b>	Not applicable
<b>Viscosity:</b>	Not applicable

### 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	Not applicable
<b>10.2 Chemical stability</b>	Not applicable
<b>10.3 Possibility of hazardous reactions</b>	Not applicable
<b>10.4 Conditions to avoid</b>	None
<b>10.5 Incompatible materials</b>	None
<b>10.6 Hazardous decomposition products</b>	None
<b>10.7 Other information</b>	None



# AMJEVITA™

## Safety Data Sheet

Revision Number: 10

Date Issued 17-Aug-2023

### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

<b>Acute Toxicity:</b>	No information available
<b>Skin corrosion/irritation:</b>	No information available
<b>Serious eye damage/eye irritation:</b>	No information available
<b>Respiratory or skin sensitization:</b>	No information available
<b>Germ cell mutagenicity:</b>	Even though this does not meet GHS classification, the following data is available: Not genotoxic in the bacterial reverse mutation assay and in vivo mouse micronucleus test.
<b>Carcinogenicity:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Reproductive toxicity:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>STOT - single exposure:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>STOT - repeated exposure:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Aspiration Hazard:</b>	No information available

### 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity

**Ecotoxicity effects:** No information available

#### 12.2 Persistence and degradability

**Persistence/Degradability:** No information available

#### 12.3 Bioaccumulative potential

**Bioaccumulation/ Accumulation:** No information available

#### 12.4 Mobility in soil

**Mobility in Environmental Media:** No information available

#### 12.5 Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment:** No information available

#### 12.6 Other adverse effects

**Other Adverse Effects:** No information available

### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

**Waste Disposal Method:** Dispose of waste according to prescribed federal, state, local and competent authority guidelines.



# AMJEVITA™

## Safety Data Sheet

Revision Number: 10

Date Issued 17-Aug-2023

### 14. TRANSPORT INFORMATION

**DOT:** Not regulated by U.S. DOT, IATA, or IMDG.

### 15. REGULATORY INFORMATION

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

##### International Inventories

**TSCA:** -  
**EINECS/ELINCS** -  
**DSL/NDSL** -  
**PICCS:** -  
**ENCS:** -  
**CHINA:** -  
**AICS:** -  
**KECL:** -

##### Legend

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances  
**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  
**IECSC** - China Inventory of Existing Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances

##### State Regulations

**California Proposition 65:** This product does not contain any Proposition 65 chemicals.

#### 15.2 Chemical safety assessment

No CSA has been conducted.



# AMJEVITA™

## Safety Data Sheet

Revision Number: 10

Date Issued 17-Aug-2023

### 16. OTHER INFORMATION

Revision Number: 10

To the best of our knowledge, the information provided here is accurate as of the date of the Safety Data Sheet (SDS). The information is specific to the material that is the subject of this SDS and may not be valid when this material is used in combination with any other materials or in any process. Each user should review the information provided here in the context of the user's intended manner of handling, using, processing, storing, transporting, and disposing of the material.

This information is provided without warranty or guarantee of any kind, whether express, implied or statutory, including without limitation warranty of fitness or merchantability for a particular purpose or noninfringement. No representation, warranty, or guarantee is made, and no liability is assumed, with respect to the material or the information contained in this SDS including without limitation its accuracy or completeness or the hazards of, or results obtained from, use of the material or the information contained here. Caution should be used in the handling, using, processing, storing, transporting, and disposing of the material.