

Date Issued 19-Sep-2024

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

#### 1.1 Product identifier Product Name: Common Name: Chemical Name: Synonyms:

AIMOVIG® Erenumab-aooe Anti-human CGRP-R (calcitonin gene-related peptide type 1 receptor) AMG 334

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against Pharmaceutical Recommended Use: Uses advised against: No information available

## Manufacturer:

1-805-447-1000

Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 INTERNATIONAL 1-703-527-3887 1-805-447-7233

# **Emergency Telephone Number:** Chemtrec

NORTH AMERICA 1-800-424-9300.

# 2. HAZARDS IDENTIFICATION

# **Emergency Overview**

Pharmaceutical product intended for clinical and commercial manufacturing purposes only. Product contains erenumab-acoe an active pharmaceutical ingredient for prophylactic treatment for migraine headaches. Dosage contents may post 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, WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA)

Does not meet GHS classification criteria and therefore is not classified. Not classified

# 2.2 Label elements

Does not meet GHS classification criteria and therefore is not classified. Not classified

2.3 Other Hazards No information available



Date Issued 19-Sep-2024

# **3. COMPOSITION/INFORMATION ON INGREDIENTS**

# 3.1 Substances

Ingredients:	See below
Chemical Name: CAS-No:	Anti-human CGRP-R (calcitonin gene-related peptide type 1 receptor) 1582205-90-0

AIMOVIG® is supplied as a single-dose prefilled syringe or single-dose prefilled SureClick® autoinjector containing either 70 mg/mL or 140 mg/mL of erenumab-aeeo formulated in sodium acetate, sucrose and polysorbate 80 at a pH of 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

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



Date Issued 19-Sep-2024

# 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.



Date Issued 19-Sep-2024

# 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 2,000 $\mu$ g/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. Erenumab-aooe has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 1 compound (1,000 $\mu$ g/m <sup>3</sup> - 5,000 $\mu$ g/m <sup>3</sup> ).
Engineering Controls:	When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.
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:	When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be based on the job activity and the potential for exposure.
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.



Date Issued 19-Sep-2024

# 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** Physical State: Molecular Weight: Odor: **Odor Threshold:** pH: Melting Point: Boiling point Flash Point: **Evaporation Rate:** Lower explosive limit: Upper explosive limit: Vapor Pressure: Vapor Density (air = 1): Relative density: Water Solubility: Partition Coefficient (log Kow): Viscosity:

Colorless to slightly yellow Liquid 150 kD No information available No information available 5.2 No information available No information available

# **10. STABILITY AND REACTIVITY**

10.1 Reactivity	No information available
10.2 Chemical stability	Not applicable
10.3 Possibility of hazardous reactions	Not applicable
10.4 Conditions to avoid	None
10.5 Incompatible materials	None
10.6 Hazardous decomposition products	No information available
10.7 Other information	None



Date Issued 19-Sep-2024

# **11. TOXICOLOGICAL INFORMATION**

# 11.1 Information on toxicological effects

Acute Toxicity: Skin corrosion/irritation: Serious eye damage/eye irritation:	No information available Does not meet GHS Classification Criteria and therefore is not classified. Does not meet GHS Classification Criteria and therefore is not classified.
Respiratory or skin sensitization:	Does not meet GHS Classification Criteria and therefore is not classified.
Germ cell mutagenicity:	Does not meet GHS Classification Criteria and therefore is not classified.
Carcinogenicity:	Does not meet GHS Classification Criteria and therefore is not classified.
Reproductive toxicity:	Does not meet GHS Classification Criteria and therefore is not classified.
STOT - single exposure:	Does not meet GHS Classification Criteria and therefore is not classified.
STOT - repeated exposure:	Does not meet GHS Classification Criteria and therefore is not classified.
Aspiration Hazard:	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.



Date Issued 19-Sep-2024

# **14. TRANSPORT INFORMATION**

DOT:

Not regulated by U.S. DOT, IATA, ADR, 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.



Date Issued 19-Sep-2024

# **16. OTHER INFORMATION**

## Revision Number: 7

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.