Tavneos®
Safety Data Sheet

Revision Number: 2 **Date Issued** 23-Oct-2025

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

1.1 Product identifier

Product Name: Tavneos®
Common Name: Avacopan, AMG 569, CCX168
Chemical Name: (2R,3S)-2-[4-(Cyclopentylamino)phenyl]-1-(2-fluoro-6-methyl-benzoyl)-N-[4-methyl-3-(trifluoromethyl)phenyl]piperidine-3-carboxamide
Synonyms: No information available

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 an active pharmaceutical ingredient, avacopan, used to block complement 5a-mediated pro-inflammatory effects in adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis. The most common and serious adverse effects include: hepatotoxicity and increased risk of infections. These effects may potentially occur if exposures repeatedly exceed the Occupational Exposure Limit described below. Avoid inhalation, skin contact, eye contact, and accidental ingestion.

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)

Chronic aquatic toxicity	Chronic 4

2.2 Label elements

SGHH0999
H413 - May cause long lasting harmful effects to aquatic life

2.3 Other Hazards

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredients: Active Ingredient - Avacopan

Chemical Name: (2R,3S)-2-[4-(Cyclopentylamino)phenyl]-1-(2-fluoro-6-methyl-benzoyl)-N-[4-methyl-3-(trifluoromethyl)phenyl]piperidine-3-carboxamide

CAS-No: 1346623-17-3

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.

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.

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 13 µg/m^3 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. Avacopan has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 4 compound (5 µg/m^3 - 20 µg/m^3).

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White to off-white tan
Physical State:	Solid
Molecular Weight:	581.66 g/mol
Odor:	No information available
Odor Threshold:	No information available
pH:	No information available
Melting Point:	No information available
Boiling point	No information available
Flash Point:	No information available
Evaporation Rate:	No information available
Lower explosive limit:	No information available
Upper explosive limit:	No information available
Vapor Pressure:	No information available
Vapor Density (air = 1):	No information available
Relative density:	No information available
Water Solubility:	Poorly soluble in water
Partition Coefficient (log Kow):	pH 5 – 6.99, pH 7 – 7.12, pH 9 – 6.98
Viscosity:	No information available

10. STABILITY AND REACTIVITY

10.1 Reactivity No information available

10.2 Chemical stability No information available

10.3 Possibility of hazardous reactions No information available

10.4 Conditions to avoid

Warning: Avacopan, the active pharmaceutical ingredient in Tavneos, can form combustible dust concentrations in air during processing and present an explosion hazard risk.
- Minimize dust generation and accumulation. Fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
- Routine housekeeping should be instituted to ensure that dust does not accumulate on surfaces.
- Dry powders are sensitive to electrostatic ignition. Provide adequate precautions, such as electrical grounding, bonding, or inert atmospheres for process equipment, and grounding and bonding of personnel who are open handling the powder.
- Appropriately classified electrical equipment should be used.
- Explosion hazards should be considered when using dust control equipment, such as local exhaust ventilation, air material separators, portable vacuums, etc.
- Antistatic or fire-retardant PPE maybe required for the task dependent on risk assessment.
- Grounding, anti-static tools, and/or an electrically rated vacuum should be used to clean up spills.
- Refer to NFPA 652, Standard on the Fundamentals of Combustible Dust

10.5 Incompatible materials No information available

10.6 Hazardous decomposition products No information available

10.7 Other information

Dust Explosion Properties:

Pmax (bar) - 7.1 ± 10%
Kst (bar m/s) - 74 ± 20%
MIE (mJ) - 10 < MIE < 30
MIT Cloud – 460oC

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity: No information available
Skin corrosion/irritation: No information available
Serious eye damage/eye irritation: No information available
Respiratory or skin sensitization: No information available
Germ cell mutagenicity: GHS classification criteria not met. Not mutagenic or genotoxic in a battery of in vitro and in vivo studies.
Carcinogenicity: GHS classification criteria not met. Did not show carcinogenic effects in animal experiments
Reproductive toxicity: GHS classification criteria not met. Avacopan is not considered to be a reproductive or development toxicant.
STOT - single exposure: Based on available data, the GHS classification criteria are not met.
STOT - repeated exposure: Based on available data, the GHS classification criteria are not met.
Aspiration Hazard: No information available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity effects: Bioaccumulation in Fish (OECD 305) - 664 L/kg
GHS Category Chronic 4

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.

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.

16. OTHER INFORMATION

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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.

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