1. Product and Company Identification

PRODUCT NAME: PRALUENT™ (alirocumab) injection, for subcutaneous use; 75 mg/mL or 150 mg/mL in a single-dose pre-filled pen or syringe

Substance name: Alirocumab

Supplier:
Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807

24-Hour Transport Emergency, US (Chemtrec):	**(800) 424-9300**
24-Hour Transport Emergency, outside US (Chemtrec):	**(703) 527-3887**
US Customer Service	**(800) 207-8049**
24-Hour Emergency, sanofi-aventis US:	**(908) 981-5550**

Product use: Pharmaceutical product.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification: Not classified as a hazardous substance or mixture.

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, alirocumab:

Signal Word: None required.

Hazard Statement(s): None required.

Symbol(s): None required.

Precautionary Statement(s):

- Prevention: None required.

- Response: None required.
- Storage: None required.
- Disposal: None required.

2.3 Hazards Not Otherwise Classified (HNOC)

None known.

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3. Composition/Information on Ingredients

Product description: Alirocumab, a fully human monoclonal antibody, in aqueous solution.

Chemical Name:	**Common Name:**	**CAS #:**	**Percentage or concentration range**
Alirocumab	Alirocumab	1245916-14-6	75 mg/mL or 150 mg/mL
α-D-Glucopyranosyl β-D-fructofuranoside	Sucrose	57-50-1	100 mg per pen or syringe
Polyoxyethylene 20 sorbitan monolaurate	Polysorbate 20	9005-64-5	0.1 mg per pen or syringe
L-Histidine	Histidine	71-00-1	6 to 8 mM per pen or syringe

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4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with product, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention if irritation develops.

Skin contact: In case of contact with product, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If product is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

The most commonly occurring adverse reactions (incidence ≥1%) from subcutaneous use in clinical trials included influenza and pruritus.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

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5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

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6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn (see Section 8).

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Absorb spilled liquid with a suitable inert material, place in suitable container for disposal and mop area.

6.4 Methods for clean-up:

Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

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7. Handling and Storage

7.1 Precautions for Safe Handling

Product should be used in a controlled work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

Store in a refrigerator at 36° to 46° F (2°C to 8°C) in the outer carton in order to protect from light. Do not freeze. Do not expose to extreme heat. Do not shake.

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8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure band, alirocumab: 10 – 100 mcg/m^3, 8-hour TWA.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for eye contact with the product.

Skin protection: Suitable protective gloves should be worn. Use of a protective or disposable gown or laboratory coat is recommended if there exists a potential for contact with the product.

Respiratory protection: None normally required for routine handling of the product. However, approved respiratory protection should be worn if there is a potential for exposure to the product. A respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 must be followed whenever workplace conditions warrant respirator usage.

General hygiene considerations: Wash hands before breaks and at the end of the work shift.

9. Physical and Chemical Properties

Appearance: Clear, colorless to pale yellow liquid (aqueous solution).
Odor: no data available.
Odor threshold: no data available.
pH: 6.0
Melting point/ Freezing point: no data available.
Initial boiling point/boiling point range: no data available.
Flash point: no data available.
Evaporation rate: no data available.
Flammability: no data available.
Upper/lower flammability or explosive limits: no data available.
Vapor pressure: no data available.
Vapor density: no data available.
Relative density: Approx. 1.08 g/cm^3
Solubility: Miscible with water.
Partition coefficient, n-octanol/water: no data available.
Auto-ignition temperature: no data available.
Decomposition temperature: no data available.
Viscosity: no data available.

10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

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11. Toxicological Information

The following information is for the active ingredient alirocumab unless otherwise noted:

Information on likely routes of exposure: Not expected under normal handling conditions. Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: The most commonly occurring adverse reactions (incidence ≥1%) from subcutaneous use in clinical trials included influenza and pruritus.

Effects of short-term (acute) exposure: Potential for allergic reactions based on clinical data.

Effects of long-term (chronic) exposure: No data available.

Acute toxicity (LD_{50}): Single-dose toxicology studies were not performed.

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: No data available.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: Carcinogenicity studies have not been conducted with alirocumab.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: Based on animal data, alirocumab is not predicted to increase the risk of developmental abnormalities.

Mutagenicity: Mutagenicity studies have not been conducted with alirocumab.

Aspiration hazard: No data available.

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12. Ecological Information

The following information is for the active ingredient alirocumab unless otherwise noted:

12.1. Ecotoxicity

No data available.

12.2. Persistence and degradability

No data available. Because alirocumab is a protein, it is expected to degrade to small peptides and individual amino acids.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No data available.

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13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

14. Transport Information

14.1 Basic shipping information, finished product

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

15. Regulatory Information

US Regulations
CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.
SARA Title III:
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.
Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Not listed.
Massachusetts Right-To-Know List: Not listed.
New Jersey Right-To-Know List: Not listed.
Pennsylvania Right-To-Know List: Not listed.

16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms
CAS: Chemical Abstracts Service
DOT: U.S. Department of Transportation
EST: Eastern standard time (U.S.)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
OEL: Occupational Exposure Limit
PPE: Personal Protection Equipment
SDS: Safety Data Sheet
STEL: Short-term exposure limit
TWA: Time-weighted average
U.S.: United States

Date Prepared: November 16, 2016; Second version.