

SAFETY DATA SHEETS

This SDS packet was issued with item:

071417260

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071417161 071417195 071417278

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071399682



1. Product and Company Identification

PRODUCT NAME: AUVI-Q™ (epinephrine injection, USP)
0.3 mg or 0.15 mg Auto-Injector

Substance name: Epinephrine

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 device.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification (epinephrine solution):

Acute toxicity - oral, Category 4

Acute toxicity - dermal, Category 4

Acute toxicity - inhalation, Category 4

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, epinephrine:

Signal Word: Warning

Hazard Statement(s): Harmful if swallowed, if inhaled or in contact with skin.

Symbol(s): Exclamation mark

Precautionary Statement(s):

- Prevention: Avoid breathing spray. Use only in a well-ventilated area. Wear protective gloves. Wash hands thoroughly after handling. Do not eat, drink or smoke while using this product.
- Response: If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center if you feel unwell. If swallowed: Call a poison center if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water and soap. Take off contaminated clothing and wash it before reuse. Call a poison center if you feel unwell.
- Storage: Store locked up.
- Disposal: Dispose of contents and container in accordance with applicable regional, national and local laws and regulations.

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

3. Composition/Information on Ingredients

<u>Chemical Name:</u>	<u>Common Name:</u>	<u>CAS #:</u>	<u>Percentage or concentration range</u>
(-)-3,4-Dihydroxy- α -[(methylamino)methyl] benzyl alcohol	Epinephrine	51-43-4	0.11 %
Sulfurous acid, monosodium salt	Sodium bisulfite	7631-90-5	0.2 %
Sodium chloride	Sodium chloride	7647-14-5	1.2 %
Hydrochloric acid		7647-01-0	Trace (used for pH adjustment)
Water	Water	7732-18-5	Balance (> 98%)

The device contains a small amount (about 1 mL) of inert gas (argon, CAS # 7440-37-1).

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.

Skin contact: In case of contact with product, immediately flush skin with plenty of soap and water. Remove contaminated clothing and shoes. Call a poison center if you feel unwell.

Ingestion: If swallowed, call a poison center. 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. Call a poison center if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache and/or respiratory difficulties.

4.3 Indication of any immediate medical attention and special treatment needed

In case of accidental injection to the digits, hands, or feet, treatment should be directed at vasodilation. See package insert for additional information.

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.

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.

7. Handling and Storage

7.1 Precautions for Safe Handling

Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Do not eat, smoke or drink while handling product. Wash hands thoroughly after handling.

7.2 Conditions for Safe Storage

Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light. Store at 20 – 25°C (68 – 77° F). Do not refrigerate.

Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure band, epinephrine: 1 - 10 micrograms/m³, 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

The following information is for the epinephrine product solution unless otherwise noted:

Appearance: Clear, colorless liquid.

Odor: No data available.

Odor threshold: No data available.

pH: 2.2 – 5.0

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: 1.006 g/cm³ at 20 °C
Solubility: No data available.
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.

11. Toxicological Information

The following information is for the active ingredient epinephrine 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: Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache and/or respiratory difficulties.

Effects of short-term (acute) exposure: Overexposure to epinephrine may cause serious and potentially fatal cardiovascular effects, including elevated arterial pressure, pulmonary edema, and transient bradycardia followed by tachycardia. See package insert.

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

Acute toxicity (LD50):

Epinephrine:

Oral LD50, rat: 4 mg/kg

Dermal LD50, rat: 62 mg/kg.

Inhalation LD50, rat: 0.00125 mg/l

Sodium bisulfite:

Oral LD50, rat: 2,000 mg/kg.

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: Sodium bisulfite: may cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons.

Epinephrine: 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: Long-term studies to evaluate the carcinogenic potential of epinephrine have not been evaluated.

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

Reproductive toxicity and teratogenicity: Epinephrine was teratogenic in rabbits, mice and hamsters. Epinephrine has been shown to have teratogenic effects when administered subcutaneously in rabbits at approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m² basis at a maternal dose of 1.2 mg/kg/day for two to three days), in mice at approximately 7 times the maximum daily subcutaneous or intramuscular dose (on a mg/m² basis at a maternal subcutaneous dose of 1 mg/kg/day for 10 days), and in hamsters at approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m² basis at a maternal subcutaneous dose of 0.5 mg/kg/day for 4 days).

These effects were not seen in mice at approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m² basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

Mutagenicity: Epinephrine and other catecholamines have been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay. Epinephrine was positive in the DNA Repair test with B. subtilis (REC) assay, but was not mutagenic in the Salmonella bacterial reverse mutation assay.

Aspiration hazard: No data available.

12. Ecological Information

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

12.1. Ecotoxicity

Acute invertebrate toxicity: EC50 = 40.0 mg/L

Species: Daphnia magna

Duration of test: 24 hours

Acute invertebrate toxicity: EC50 = 31.7 mg/L

Species: Daphnia magna

Duration of test: 48 hours

12.2. Persistence and degradability

Biological degradability: approx. 41%; not readily biodegradable.

Duration of test: 28 days

12.3. Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

No data available

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.

Epinephrine (CAS # 51-43-4) is a RCRA listed hazardous waste, code P042.

The device contains two lithium button cell batteries and a small steel gas cell containing about 1 mL of argon.

California regulations: This product uses batteries containing perchlorate material.

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

AUVI-Q™ contains two lithium metal batteries and should be shipped according to the current regulatory requirements applicable for lithium metal batteries contained in equipment and based on the mode of transport.

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

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Second version.