

SAFETY DATA SHEETS

This SDS packet was issued with item:

078433863

N/A



1. Product and Company Identification

PRODUCT NAME: ANZEMET® Injecton (multidose vials)

Substance name: dolasetron mesylate

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:

Eye damage/irritation, Category 2A

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 product:

Signal Word: Warning

Hazard Statement(s): Causes serious eye irritation.

Symbol(s): Exclamation mark.

Precautionary Statement(s):

- Prevention: Wear eye protection. Wash hands thoroughly after handling.
- Response: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.
- Storage: None required.
- Disposal: None required.

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>
1H-Indole-3-carboxylic acid, (2a,6a,8a,9ab)-octahydro-3-oxo-2,6- methano-2H-quinolizin-8-yl ester, monomethanesulfonate, hydrate	Dolasetron mesylate	115956-13-3	20 mg/mL (1.9%)
Phenol	Phenol	75-71-8	5 mg/mL (< 1%)
Mannitol	Mannitol	64-17-5	29 mg/mL (2.8%)
Water for injection	Water for injection	7732-18-5	Balance (> 95%)

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 water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician immediately. 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

Hypotension, headache, dizziness, fatigue, bradycardia or tachycardia, gastrointestinal effects.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

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

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 at 20–25°C (68–77°F) with excursions permitted to 15–30°C (59–86°F). Protect from light.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, dolasetron mesylate: 0.060 mg/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

Appearance: Clear, colorless liquid.

Odor: No data available.

Odor threshold: No data available.

pH: 3.2 to 3.8

Melting point/ Freezing point: Not applicable.

Initial boiling point/boiling point range: Not applicable.

Flash point: No data available.

Evaporation rate: Not applicable.

Flammability: No data available.

Upper/lower flammability or explosive limits: No data available.

Vapor pressure: Not applicable.

Vapor density: Not applicable.

Relative density: No data available.

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 dolasetron mesylate 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: Hypotension, headache, dizziness, fatigue, bradycardia or tachycardia, gastrointestinal effects.

Effects of short-term (acute) exposure: Hypotension, headache, dizziness, fatigue, bradycardia or tachycardia, gastrointestinal effects.

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

Acute toxicity (LD50):

Oral route, rat: 446 mg/kg

Oral route, mouse: 545 mg/kg.

Skin corrosion/irritation: Slight dermal irritant based on animal studies.

Serious eye damage/irritation: Risk of serious damage to eyes based on animal studies.

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: In a 24 month carcinogenicity study, there was a statistically significant increase in the incidence of combined hepatocellular adenomas and carcinomas in male mice treated with 150 mg/kg/day and above.

In a 24 month rat carcinogenicity study, oral dolasetron mesylate was not tumorigenic at doses up to 150 mg/kg/day in male rats and 300 mg/kg/day in female rats.

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

Reproductive toxicity and teratogenicity: Teratology studies have not revealed evidence of impaired fertility or harm to the fetus due to dolasetron mesylate. Dolasetron mesylate was found to have no effect on fertility and reproductive performance at oral doses up to 100 mg/kg/day in female rats and up to 400 mg/kg/day in male rats.

Mutagenicity: Dolasetron mesylate was not genotoxic in the Ames test, the rat lymphocyte chromosomal aberration test, the Chinese hamster ovary cell forward mutation test, the rat hepatocyte unscheduled DNA synthesis test or the mouse micronucleus test.

Aspiration hazard: No data available.

12. Ecological Information

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

12.1. Ecotoxicity

Acute toxicity in *Daphnia magna*: 48-hour EC50 and NOEC of 50 and 25 mg/L, respectively.

Acute toxicity in bluegill fish (*Lepomis macrochirus*): 96-hour LC50 and NOEC of 21 and 8.5 mg/L, respectively.

Acute toxicity in earthworms (*Lumbricus terrestris*): LC50 > 982 mg/kg soil.

Microbial growth inhibition: No inhibition was observed for *Pseudomonas fluorescens*, *Azobacter chroococcum*, *Aspergillus clavatus* and *Penicillium canescens* up to 1000 mg/L. The MICs for *Bacillus megaterium*, *Anabaena flos-aquae*, and *Chaetomium globosum* were 800, 200, and 800 mg/L, respectively.

12.2. Persistence and degradability

Biological degradability: Aerobic biodegradation in soils: Mineralization half-lives of 113-659 days for sandy, silt and loam soils, indicating significant biotransformation.

Aqueous photodegradation in water: Half-lives of 76-112 hours, in pH 5, 7 and 9 light-exposed aqueous buffers. Complete degradation within 6 hours under indirect photodegradation.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

Soil/sediment adsorption-desorption: In clay loam, a Koc value of 3855 indicates slight mobility; in sandy and silt loam Koc values of 25536 and 8066 indicate immobility.

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.

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

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