SAFETY DATA SHEETS

This SDS packet was issued with item:

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N/A

MATERIAL SAFETY DATA SHEET

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1. PRODUCT IDENTIFICATION

Product Name(s): ANZEMET Injection and Multi-Dose Vials

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

2. HAZARDS IDENTIFICATION

Appearance: Anzemet Injection and Multidose vials contain a clear, colorless, nonpyrogenic, sterile solution for intravenous administration.

Anzemet (dolesetron mesylate) is an antinauseant antiemetic agent. Dolasetron Mesylate is a highly specific and selective serotonin subtype 3 (5-HT_3) receptor antagonist both in vitro and in vivo.

Anzemet is contraindicated in patients known to have hypersensitivity to this drug.

Anzemet solution may cause eye and skin irritation.

Chronic Effects/Carcinogenicity
See Section 11 for toxicology information.

3. COMPOSITION & INFORMATION ON INGREDIENTS

Component	CAS#
Dolasetron mesylate	115956-13-3
Phenol	75-71-8
Mannitol	64-17-5
Water for injection	7732-18-5

Product does not contain any NTP, OSHA, or IARC carcinogens.

4. FIRST AID MEASURES

Eyes: Flush thoroughly with water for 15 minutes; seek medical attention if irritation persists.

Skin: Flush thoroughly with water for 15 minutes; seek medical attention if irritation persists.

Ingestion: If large amount is ingested, seek medical attention.

Note to Physician
Additional details are available in Section 11, on the package insert or in the Physicians' Desk Reference.

5. FIRE FIGHTING MEASURES

General Hazards
In case of fire and/or explosion do not breathe fumes. CO, CO2, and oxides of nitrogen and may be generated in a fire.

Fire Fighting Extinguishing Media
In case of fire use waterspray, foam or dry chemical.

Fire Fighting Instructions
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.

Hazardous Combustion Products
CO, CO2 and oxides of nitrogen and may be generated in a fire.

6. ACCIDENTAL RELEASE MEASURES

Steps to be taken in case material is released or spilled: Wear protective gloves and eye protection. Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container.

Waste Disposal Methods: Dispose according to local, state and/or federal regulations.

7. HANDLING AND STORAGE

Special Handling
Protect product from physical damage.

Special Storage
Store at controlled room temperature 68-77^0 F, with excursions permitted to 59-86^0 F. Protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye Protection Clean-up, manufacturing and packaging operations require safety glasses or goggles.

Skin Protection Latex gloves or gloves of equal or greater protection are recommended for spill clean-up, manufacturing and packaging operations. If in solution, gloves impervious to the solvent used should be worn.

Respiratory Protection Clean-up, manufacturing and packaging operations may require respiratory protection based upon potential exposures to individual ingredients.

Engineering Controls Handle all powder forms of this compound in a properly certified fumehood to control exposure below any designated permissible exposure limit. Solutions and suspensions may be handled outside of a hood with appropriate spill protection and solvent resistant gloves.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form: Clear colorless liquid.
pH of Solution: 3.2 to 3.7.

10. STABILITY AND REACTIVITY

Incompatibility
Heat and strong oxidizers.

Hazardous Decomposition Products
No data.

Hazardous Polymerization
Will not occur.

General Information
No additional information.

11. TOXICOLOGICAL INFORMATION

Single intravenous doses of dolasetron mesylate at 160 mg/kg in male mice and 140 mg/kg in female mice and rats of both sexes (6.3 to 12.6 times the recommended human dose based on body surface area) were lethal. Symptoms of acute toxicity were tremors, depression and convulsions.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

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.

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.

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.

Teratology studies have not revealed evidence of impaired fertility or harm to the fetus due to dolasetron mesylate. These studies have been performed in pregnant rats at oral doses up to 100 mg/kg/day and pregnant rabbits at oral doses up to 100 mg/kg/day. There are. however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

12. ECOLOGICAL INFORMATION

Dolasetron mesylate:
Aerobic biodegradation in water: No significant mineralization; approximately 37.8 % and 2.0% was biotransformed to a non-polar and more polar degradation product, respectively. Biotransformation half-life estimate of approximately 35 days, suggesting a potential removal pathway.

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, indicating a possibly important removal mechanism.

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

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.

Acute toxicity in *Daphnia magna*: 48-hour EC_{50} and NOEC of 50 and 25 mg/L, respectively.
Acute toxicity in bluegill fish (*Lepomis macrochirus*): 96-hour LC_{50} and NOEC of 21 and 8.5 mg/L, respectively.
Acute toxicity in earthworms (*Lumbricus terrestris*): $LC_{50} > 982$ mg/kg soil.

13. DISPOSAL CONSIDERATIONS

Disposal Information

Waste must be disposed of in accordance with federal, state and local environmental regulations. Waste may be placed in a leakproof, puncture resistant container which is then placed in disposable wire-tie or sealable 4-mil-thick polyethylene or 2-mil-thick propylethylene bags.

Waste Disposal Methods

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

14. TRANSPORT INFORMATION

Not a regulated material for transport.

15. REGULATORY INFORMATION

CERCLA

Not listed.

SARA Title III

Not listed.

SARA 313

Not listed.

16. OTHER INFORMATION

Other Information

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