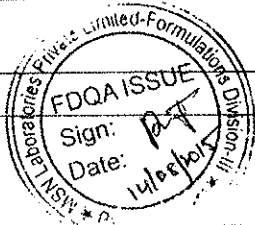
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	MATERIAL SAFETY DATA SHEET	
Product Name	FOSAPREPITANT DIMEGLUMINE FOR INJECTION 150 mg/Vial	



1. Product Information

Product Name: Fosaprepiatnt Dimeglumine for injection 150 mg/Vial

2. Composition/Information on Ingredients

C.A.S. No : 265121-04-8
Molecular Formula : $C_{23}H_{22}F_7N_4O_6P \cdot 2(C_7H_{17}NO_5)$
Molecular Weight : 1004.83
Chemical Name : 1-Deoxy-1-(methylamino)-D-glucitol[3-[[[(2R,3S)-2-[(1R)-1-[3,5-bis(trifluoromethyl)phenyl]ethoxy]-3-(4-fluorophenyl)-4-morpholinyl]methyl]-2,5-dihydro-5-oxo-1H-1,2,4-triazol-1-yl]phosphonate (2:1) (salt)

3. Hazards Identification

Emergency Overview:

Appearance:

Color: White to off-white

Form : Powder.

Odor: Odorless

Signal words: WARNING!

Potential Health Effects: General Causes serious eye irritation. May cause skin irritation. May cause central nervous system effects. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Do not ingest. Avoid release to the environment.

Inhalation: No data available.

Skin: Active pharmaceutical ingredient: Causes skin irritation.

Eye: Active pharmaceutical ingredient: Causes serious eye damage.

Ingestion: Harmful if swallowed.

Chronic Effects: This compound is used as an anti-emetic agent. In clinical use adverse reactions include: hiccups, fatigue, effects on liver enzymes, constipation, headache and anorexia. Allergic reactions have been reported.

Routes of Exposure: Inhalation


Target Organs: central nervous system

OSHA Regulatory Status: This product is hazardous according to OSHA 29CFR 1910.1200.

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Environment: May cause long-term adverse effects in the aquatic environment.

4. First Aid Measures

Inhalation: Move into fresh air and keep at rest. For breathing difficulties, oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Contact physician if larger quantity has been consumed.

Notes to the physician: Hazards: Fosaprepitant is a prodrug and rapidly converted to Aprepitant. This compound is used as an anti-emetic agent. See current prescribing information.

Treatment: Treat supportively and symptomatically

5. Fire Fighting Measures

Extinguishing media: Water spray, fog, CO2, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.


Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply

6. Accidental Release Measures

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures.

Environmental precautions: Do not release into the environment.

Spill Cleanup Methods: Small Liquid Spills: Absorb up with sand or other non-combustible absorbent material. Large quantities should not be discharged into the drain but removed with absorbing material. For waste disposal. Prevent runoff from entering drains, sewers, or streams.

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7.. Handling and Storage

Handling: Avoid breathing mists or vapors. Avoid exposure - obtain special instructions before use. Wash thoroughly after handling.

Storage: Refrigeration required (2 - 8C). Keep container tightly closed in a cool, wellventilated place.

8. Exposure Controls/Personal Protection

Protective Measures: Use feasible engineering controls to minimize exposure to compound.

Respiratory Protection: Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed. Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.

Hand protection: Chemical resistant gloves

Eye protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Work uniform or laboratory coat.

Hygiene measures: Wash skin thoroughly with soap and water.

9. Physical and Chemical Properties


- Appearance:**
- Physical State:** Solid
- Form:** Powder.
- Color:** White to off-white
- Odor:** Odorless

10. Stability and Reactivity

- Possibility of hazardous reactions:** Stable
- Conditions to avoid:** Moisture. Excessive heat.
- Incompatible materials:** None under normal conditions.
- Hazardous decomposition products:** Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

11. Toxicological Information

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

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Product:

Acute Toxicity (Dermal): No data available.

Acute Toxicity (Inhalation): No data available.

Specified substance(s):

Acute Toxicity (Oral);

Name	Test results
FOSAPREPITANT DIMEGLUMINE	LD50 (Rat): > 500 mg/kg LD50 (Mouse): > 500 mg/kg

Repeated dose toxicity:

Name :	Test results
FOSAPREPITANT DIMEGLUMINE	Repeated exposure to in rats, dogs and monkeys in the blood, kidneys, liver, thyroid, prostate, and testes.

Inhalation: No data available.

Ingestion: Harmful if swallowed.

Skin corrosion/irritation: Preparation may cause skin irritation. Active pharmaceutical ingredient: Moderately irritating to the skin.

Serious eye damage/eye irritation: Preparation may cause eye irritation. Active pharmaceutical ingredient: Severely irritating to eyes.


Respiratory sensitizer/Skin sensitizer: The active pharmaceutical ingredient has been reported to be non-sensitizing.

Carcinogenicity: No component in this product is listed as a carcinogen by OSHA, NTP, or IARC. Active pharmaceutical ingredient: Benign liver and thyroid tumors were observed in rats. Fibrosarcomas were found in high dose male mice.

Mutagenesis: Negative in a battery of in vitro and in vivo genotoxicity assays.

Reproductive toxicity: Active pharmaceutical ingredient: No adverse reproductive or developmental effects observed in rats and rabbits.

Other Effects: This compound is used as an anti-emetic agent. The most common adverse effects reported in clinical trials include: hiccups, fatigue, effects on liver enzymes, constipation, headache and anorexia. Allergic reactions have been reported. Repeated exposure in rats, dogs and monkeys caused changes in the blood, kidneys, liver, thyroid, prostate, and testes.

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12. Ecological Information

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: May cause long-term adverse effects in the aquatic environment.

Product:

Chronic Toxicity(Fish): No data available.

Chronic Toxicity(Aquatic invertebrates): No data available.

Specified substance(s):

Acute toxicity(Fish):

Name	Test results
FOSAPREPITANT DIMEGLUMINE	LC 50 (Fathead Minnow, 96 h): Estimated Non-toxic@ limit of solubility

Acute toxicity(Aquatic invertebrates):

Name	Test results
FOSAPREPITANT DIMEGLUMINE	LC 50 (Water flea (Daphnia magna), 96 h): Estimated Not toxic@ limit of solubility

Acute toxicity(Aquatic plants):

Name	Test results
FOSAPREPITANT DIMEGLUMINE	LC 50 (Green algae (Selenastrum capricornutum), 72 h): Estimated Not toxic@ limit of solubility

Persistence and degradability:


This material is expected to hydrolyze to Aprepitant.

Bioaccumulative potential:

Active pharmaceutical ingredient: This material is expected to hydrolyze to Aprepitant. Aprepitant is poorly soluble. Has the potential to bioaccumulate.

Mobility:

Not determined for finished product. The active pharmaceutical ingredient is expected to partition to sediment and wastewater solids.

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13. Disposal Considerations

Disposal Methods: Disposal must be in accordance with applicable national, state/provincial, and/or local regulations.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14. Transport Information

- DOT - Department of Transportation**
Not regulated.
- IMDG - International Maritime Dangerous Goods Code**
Not regulated.
- IATA - International Air Transport Association**
Not regulated

15. Regulatory Information

US Regulations


- **CERCLA Hazardous Substance List (40 CFR 302.4):**
None
- **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**
None
- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**
None

SARA Title III

- **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**
None
- **Section 313 Toxic Release Inventory (40 CFR 372):**
None present or none present in regulated quantities.



State Regulations

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**
No ingredient regulated by CA Prop 65 present.
- **Massachusetts Right-To-Know List:**
No ingredient regulated by MA Right-to-Know Law present.
- **New Jersey Right-To-Know List:**
No ingredient regulated by NJ Right-to-Know Law present.
- **Pennsylvania Right-To-Know List:**
No ingredient regulated by PA Right-to-Know Law present.

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16. Other Information

OTHER INFORMATION This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

	Prepared By	Checked By
Sign		
Date	13/08/2015	13/08/2015