Aspiro Pharma Limited
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Hyderabad 500018, Telangana State, India
Tel: +91-40-23704925,Fax:+91-04023704926
Web: www.aspiropharma.com
CIN No.:U24100TG2014PLC092771

SAFETY DATA SHEET

Section 1: Identification	
GHS Product identifier	Fosaprepitant Dimeglumine for Injection 150 mg/vial
Trade Name	--
Recommended use	Pharmaceutical product
Manufacturer	**Aspiro Pharma Limited,** Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	**Camber Pharmaceuticals, Inc.,** Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
General	Finished pharmaceutical product. Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Very toxic to aquatic life with long lasting effects. Avoid release to the environment.
Potential Physical / Chemical Effects:	This material may present a dust deflagration hazard if sufficient quantities are or may become suspended in air. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.
Environment:	Very toxic to aquatic life with long lasting effects.

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Fosaprepitant Dimeglumine	265121-04-8

Section 4: First-Aid Measures	
Eye Contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
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.
Ingestion	Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an

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	unconscious person. Contact physician if larger quantity has been consumed
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.
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.
Section 5: Fire-Fighting Measures	
Suitable 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.
Protective Measures:	Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.
special firefighting procedures	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.
Environmental precautions	Do not release into the environment.
Spill Cleanup Methods:	Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

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Section 7: Handling and Storage	
Handling	Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Vials must be refrigerated, store at 2°C to 8°C (36°F to 46°F). The reconstituted final drug solution is stable for 24 hours at ambient room temperature [at or below 25°C (77°F)].
Section 8: Exposure Controls/Personal Protection	
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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin, Hand and body protection:	Work uniform or laboratory coat. Chemical resistant gloves.
Protective Measures:	Observe occupational exposure limits and minimize the risk of inhalation of dust. 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. Powered air filter respirator. 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.
Hygiene measures:	Wash skin thoroughly with soap and water.

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Section 9: Physical and Chemical Properties	
Section 9, Physical and chemical properties	
Physical State	Solid
Form:	Powder or cake
Colour	White to off-white
Odor	NA
Description	Single dose glass vial containing 150 mg of fosaprepitant as a white to off-white lyophilized powder for reconstitution. Supplied as follows: 1 vial per carton NDC 31722-165-31
Section 10: Stability and Reactivity	
Stability:	Stable
Possibility of Hazardous Reactions	Stable
Conditions to avoid	Moisture. Excessive heat.
Incompatible materials	No data available
Hazardous decomposition Products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.
Section 11: Toxicological Information	
General Information	The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.
Acute Toxicity (Dermal)	No data available
Acute Toxicity (Inhalation)	No data available
Ingestion	Harmful if swallowed.
Skin corrosion/irritation	Active pharmaceutical ingredient: Moderately irritating to the skin.
Serious eye damage/eye irritation	Active pharmaceutical ingredient: Severely irritating to eyes.
Respiratory sensitizer/Skin sensitizer	Active pharmaceutical ingredient: Not a skin sensitizer.
Carcinogenicity	Active pharmaceutical ingredient: Benign liver and thyroid tumors were observed in rats. Not listed as carcinogen by OSHA, NTP or IARC. Fibrosarcomas were found in high dose male mice. A similar monoclonal antibody tested negative for carcinogenicity in mice. An increase in lymphomas and other malignancies were reported with clinical use of a similar monoclonal antibody.

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Mutagenesis	Active pharmaceutical ingredient: 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.

Section 12: Ecological Information

General information	The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.
Persistence and degradability	Active pharmaceutical ingredient: Not expected to degrade.
Bio-accumulative Potential	Active pharmaceutical ingredient: Not expected to bioaccumulate.
Mobility	Active pharmaceutical ingredient: Mobility varies based on soil type.

Section 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.

Section 14: Transport Information

DOT	Not regulated
IMDG - International Maritime Dangerous Goods Code	
UN number	UN3077
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(FOSAPREPITANT DIMEGLUMINE)
Class	9
Packing group	III
Label(s)	9
Subsidiary risk label Marine Pollutant / EmS No.	Envir. Hazardous, Labels Only F-A; S-F
IATA - International Air Transport Association	
UN number	UN3077
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(FOSAPREPITANT DIMEGLUMINE)
Class	9
Packing group	III
Label(s) Subsidiary risk label	9MI

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Section 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.

Section 16: Other Information

Issue Date : 05-08-2021

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Aspiro Pharma Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Aspiro Pharma Limited reserves the right to revise this SDS.