
 <b>Pharmaceutical Division</b>	<b>Fosaprepitant for Injection</b>		<b>Safety Data Sheet (SDS)</b>	
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### Section 1 - Identification


- (a) **Product Identifier:** Fosaprepitant for Injection
- (b) **Product Code(s):** 70860-780, 70860-782, 70860-783
- Common/Trade Name:** Fosaprepitant for Injection
- Chemical Name:** {3-[[[(2R,3S)-2-[(1R)-1-[3,5-Bis (trifluoromethyl) phenyl] ethoxy]-3-(4-fluorophenyl) morpholine- 4-yl) methyl]-5-oxo-4,5-dihydro-1H-1,2,4-triazole-1-yl] phosphonic acid, bis [1-deoxy-1-(methylamino)-D-glucitol] salt Sorbitan monooleate, ethoxylated Glycine, N,N'-1,2-ethanediylbis[N(carboxymethyl)-, sodium salt, hydrate (1:2:2)
- Chemical Family:** P/neurokinin-1 (NK1) receptor antagonist
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification


- (a) **GHS Classification of substance or mixture:**
- US OSHA:**
- COMBUSTIBLE DUSTS
- H302** ACUTE TOXICITY (oral) - Category 4
- H332** ACUTE TOXICITY (inhalation) - Category 4
- H315** SKIN IRRITATION - Category 2
- H319** EYE IRRITATION - Category 2A
- H335** SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
- H373** SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (prostate, respiratory tract, testes) - Category 2
- Percentage of the mixture consisting of ingredient(s) of unknown acute dermal toxicity: 99.8%
- Percentage of the mixture consisting of ingredient(s) of unknown acute inhalation toxicity: 97.2%

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**(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):**

<b>GHS Signal Word:</b>	Warning
<b>GHS Hazard Statement:</b>	<p>May form combustible dust concentrations in air.  H302 + H332 - Harmful if swallowed or if inhaled. H319 - Causes serious eye irritation.  H315 - Causes skin irritation.  H335 - May cause respiratory irritation.  H373 - May cause damage to organs through prolonged or repeated exposure. (prostate, respiratory tract, testes)</p>
<b>GHS Symbols:</b>	
<b>GHS Precautionary Statements:</b>	<p><b>Prevention</b> :</p> <p>P280 - Wear protective gloves. Wear eye or face protection.  P271 - Use only outdoors or in a well-ventilated area.  P260 - Do not breathe dust or mist.  P270 - Do not eat, drink or smoke when using this product.  P264 - Wash hands thoroughly after handling.</p> <p><b>Response</b> :</p> <p>P314 - Get medical attention if you feel unwell.  P304 + P340 + P312 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.  P301 + P312 + P330 - IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.  P302 + P352 + P362+P364 - IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse.  P332 + P313 - If skin irritation occurs: Get medical attention.  P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P337 + P313 - If eye irritation persists: Get medical attention.</p>
<b>Other Hazards</b>	Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.

**(d) Unknown Acute Toxicity** N/A


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### Section 3 – Composition / Information on Ingredients

**Product Code 70860-780**

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
{3-[[[(2R,3S)-2-[(1R)-1-[3,5-Bis(trifluoromethyl) phenyl] ethoxy]-3-(4-fluorophenyl) morpholine-4-yl] methyl]-5-oxo-4,5-dihydro-1H-1,2,4-triazole-1-yl] phosphonic acid, bis [1-deoxy-1-(methylamino)-D-glucitol] salt Sorbitan monooleate, ethoxylated Glycine, N,N'-1,2-ethanediyldis[ N(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Fosaprepitant Dimeglumine	245.3 mg	265121-04-8	N/A
Lactose Anhydrous	Lactose Anhydrous	375 mg	63-42-3	N/A
Polysorbate 80, NF	Polysorbate	75 mg	9005-65-6	N/A
EDTA Disodium, USP	Edetate Disodium	18.8 mg	6381-92-6	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s.* to pH	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s.* to pH	7647-01-0	N/A


\*q.s – quality sufficient

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**Product Code 70860-782**

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
{3-[[[(2R,3S)-2-[(1R)-1-[3,5-Bis(trifluoromethyl) phenyl] ethoxy]-3-(4-fluorophenyl) morpholine-4-yl] methyl]-5-oxo-4,5-dihydro-1H-1,2,4-triazole-1-yl] phosphonic acid, bis [1-deoxy-1-(methylamino)-D-glucitol] salt Sorbitan monooleate, ethoxylated Glycine, N,N'-1,2-ethanediybis[N(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Fosaprepitant Dimeglumine	245.3 mg	265121-04-8	N/A
Lactose Anhydrous	Lactose Anhydrous	375 mg	63-42-3	N/A
Polysorbate 80, NF	Polysorbate	75 mg	9005-65-6	N/A
EDTA Disodium, USP	Edetate Disodium	5.4 mg	6381-92-6	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s.* to pH	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s.* to pH	7647-01-0	N/A

\*q.s – quality sufficient

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(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
{3-[[[(2R,3S)-2-[(1R)-1-[3,5-Bis(trifluoromethyl) phenyl] ethoxy]-3-(4-fluorophenyl) morpholine-4-yl] methyl]-5-oxo-4,5-dihydro-1H-1,2,4-triazole-1-yl] phosphonic acid, bis [1-deoxy-1-(methylamino)-D-glucitol] salt Sorbitan monooleate, ethoxylated Glycine, N,N'-1,2-ethanediybis[N(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Fosaprepitant Dimeglumine	245.3 mg	265121-04-8	N/A
Lactose Monohydrate	Lactose Monohydrate	395 mg	10039-26-6	N/A
Polysorbate 80, NF	Polysorbate	75 mg	9005-65-6	N/A
EDTA Disodium, USP	Edetate Disodium	5.4 mg	6381-92-6	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s.* to pH	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s.* to pH	7647-01-0	N/A

\*q.s – quality sufficient

#### Section 4 – First Aid Measures

- Eye Exposure:** Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Skin Exposure:** Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

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**Ingestion:** keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.


**Inhalation:** Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

**Notes to Physician:** Treat symptomatically and supportively. See patient package insert in shipping carton for complete information.

**Section 5 – Fire-fighting Measures**

- (a) **Extinguishing Media**      Use dry chemical powder. **Do not use water jet.**
- (b) **Hazardous Thermal Decomposition Products:**      Decomposition products may include the following materials:
  - Carbon Dioxide
  - Carbon Monoxide
  - Nitrogen Oxides
  - Carbonyl Halides
  - Metal Oxide/Oxides
  - Toxic Gases
- (c) **Special Protective Equipment / Precautions:**      Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
- (d) **Special Protective Actions For Fire Fighters**      Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

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### Section 6 - Accidental Release Measures

<b>Spill:</b>	<p><b>Small Spill:</b> Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.</p> <p><b>Large Spill:</b> Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.</p>
<b>Environmental Precautions</b>	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

### Section 7 - Handling and Storage

<b>Precautions for safe handling:</b>	<p><b>Protective Measures:</b> Put on appropriate personal protective equipment (see Section 8). Do not breathe dust. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.</p> <p><b>General occupational hygiene:</b> Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.</p>
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**Storage Conditions:** Store refrigerated between 2° and 8°C (36° and 46°F).

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## Section 8 - Exposure Controls / Personal Protection

### (a) Exposure Limits

Compound	Exposure Limit
Lactose	NE
{3-[[[(2R,3S)-2-[(1R)-1-[3,5-Bis (trifluoromethyl) phenyl] ethoxy]-3- (4-fluorophenyl) morpholine-4-yl) methyl]-5-oxo-4,5-dihydro-1H-1,2,4-triazole-1-yl] phosphonic acid, bis [1-deoxy-1-(methylamino)-D- glucitol] salt Sorbitan monooleate, ethoxylated Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	NE
Sodium Hydroxide	<b>ACGIH TLV (United States, 3/2019).</b> C: 2 mg/m <sup>3</sup> <b>NIOSH REL (United States, 10/2016).</b> CEIL: 2 mg/m <sup>3</sup> <b>OSHA PEL (United States, 5/2018).</b> TWA: 2 mg/m <sup>3</sup> 8 hours.
Hydrochloric Acid	<b>ACGIH TLV (United States, 3/2019).</b> C: 2 ppm <b>NIOSH REL (United States, 10/2016).</b> CEIL: 5 ppm CEIL: 7 mg/m <sup>3</sup> <b>OSHA PEL (United States, 5/2018).</b> CEIL: 5 ppm CEIL: 7 mg/m <sup>3</sup>


### (b) Engineering Controls

Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

### (c) Individual Protection Measures

<b>Respiratory Protection:</b>	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
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<b>Eye Protection:</b>	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles. If operating conditions cause high dust concentrations to be produced, use dust goggles
<b>Skin Protection:</b>	<p><b>Hand Protection:</b> Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.</p> <p><b>Body Protection:</b> Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product</p> <p><b>Other Skin Protection::</b> Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.</p>

### Section 9 - Physical and Chemical Properties

(a)	<b>Appearance</b>	White to off-white, Solid. [Powder. (lyophilized)]
(b)	<b>Odor</b>	Not available
(c)	<b>Odor Threshold</b>	Not available
(d)	<b>pH</b>	Not available
(e)	<b>Melting Point:</b>	Not available
(f)	<b>Initial Boiling Point:</b>	Not available
(g)	<b>Flash Point</b>	Not available
(h)	<b>Evaporation Rate:</b>	Not available
(i)	<b>Flammability</b>	Not available
(j)	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
(k)	<b>Vapor Pressure:</b>	Not available
(l)	<b>Vapor Density:</b>	Not available
(m)	<b>Relative Density</b>	Not available
(n)	<b>Solubility(ies)</b>	Freely soluble in cold and hot water
(o)	<b>Partition Coefficient: n-octanol/water</b>	Not available

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(p)	<b>Auto-ignition Temperature</b>	Not available
(q)	<b>Decomposition Temperature</b>	Not available
(r)	<b>Viscosity</b>	Not available

**Section 10 - Stability and Reactivity**

(a)	<b>Reactivity</b>	Not determined
(b)	<b>Chemical Stability</b>	Stable under standard use and storage conditions.
(c)	<b>Possibility of Hazardous Reactions</b>	Under normal conditions of storage and use, hazardous reactions will not occur.
(d)	<b>Conditions to Avoid</b>	Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation.
(e)	<b>Incompatible Materials</b>	Reactive or incompatible with the following materials: oxidizing materials Reactive or incompatible with the following materials: moisture.
(f)	<b>Hazardous Decomposition Products</b>	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

**Section 11 - Toxicological Information**

(a)	<b>Likely Routes of Exposure</b>	Oral, Dermal, Inhalation.
(b)	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	<i>Eye contact</i> : pain or irritation, watering redness <i>Inhalation</i> : respiratory tract irritation, coughing <i>Skin contact</i> : irritation, redness <i>Ingestion</i> : No specific data.
(c)	<b>Delayed and immediate effects from short and long term exposure</b>	Not available

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<b>(d)</b>	<b>Potential Chronic Health Effects</b>	<p><b>General:</b> May cause damage to organs through prolonged or repeated exposure. Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.</p> <p><b>Carcinogenicity:</b> No known significant effects or critical hazards.</p> <p><b>Mutagenicity:</b> No known significant effects or critical hazards.</p> <p><b>Teratogenicity:</b> No known significant effects or critical hazards.</p> <p><b>Developmental effects:</b> No known significant effects or critical hazards.</p> <p><b>Fertility effects:</b> No known significant effects or critical hazards.</p>
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**(d) Acute Toxicity**

Component	Result	Species	Dose
Lactose	LD <sub>50</sub> Oral	Rat	>10 g/kg
Sorbitan monooleate, ethoxylated	LD <sub>50</sub> Oral	Rat	36708 mg/kg
Glycine, N,	LD <sub>50</sub> Oral	Rat	34500 uL/kg
N'-1,2-ethanediylbis[N- (carboxymethyl)-, sodium salt, hydrate (1:2:2)	LD <sub>50</sub> Oral	Rat	2214.37 mg/kg
Sodium Hydroxide	LD <sub>50</sub> Dermal	Rabbit	1350 mg/kg

**Numerical measures of toxicity**

*Acute toxicity estimates*

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Fosaprepitant for Injection, 150 mg/vial {3-[(2R,3S)-2-[(1R)-1-[3,5-Bis (trifluoromethyl) phenyl] ethoxy]-3-(4-fluorophenyl) morpholine-4-yl) methyl]-5-oxo-4,5-dihydro-1H-1,2,4-triazole-1-yl} phosphonic acid, bis [1-deoxy-1-(methylamino)-D- glucitol] salt	1437.4 500	N/A N/A	N/A N/A	N/A N/A	1.6 N/A
Sorbitan monooleate, ethoxylated	36708	N/A	N/A	N/A	N/A
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	2214.37	N/A	N/A	N/A	1.5
sodium hydroxide	N/A	1350	N/A	N/A	N/A

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### Section 12 - Ecological Information

#### (a) Ecotoxicity

Product/ingredient name	Result	Species	Exposure
Glycine, N, N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Chronic NOEC 25 mg/l Fresh water	<i>Daphnia</i>	21 days
sodium hydroxide	Acute EC50 40.38 mg/l Fresh water	<i>Crustaceans - Ceriodaphnia dubia - Neonate</i>	48 hours
	Acute LC50 125 ppm Fresh water	<i>Fish - Gambusia affinis - Adult</i>	96 hours
Hydrochloric acid	Acute LC50 240000 µg/l Marine water	<i>Crustaceans - Carcinus maenas - Adult</i>	48 hours
	Acute LC50 282 ppm Fresh water	<i>Fish - Gambusia affinis - Adult</i>	96 hours

#### (b) Persistence and degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Sorbitan monooleate, ethoxylated	-	-	Readily

- (c) **Bioaccumulative potential** Lactose : low potential
- (d) **Mobility in soil** Not available
- (e) **Other Adverse Effects** No known significant effects or critical hazards.

### Section 13 - Disposal Considerations


The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues.

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains

### Section 14 - Transport Information

**DOT:** Non-bulk packages of this product are not regulated as hazardous materials unless transported by inland waterway. This product is not regulated as a hazardous material when transported in sizes of ≤5 L or ≤5 kg, provided the packaging meet the general provisions of §§ 173.24 and 173.24a.

**Limited quantity** Yes.

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**Packaging instruction** Exceptions: 155. Non-bulk: 213. Bulk: 240.

**Special provisions** 8, 146, 335, 384, A112, B54, B120, IB8, IP3, N20, N91, T1, TP33

<b>(a)</b>	<b>UN Number</b>	UN3077
<b>(b)</b>	<b>UN Proper Shipping Name</b>	Environmentally hazardous
<b>(c)</b>	<b>Transport Hazard Class(es)</b>	9
<b>(d)</b>	<b>Packing Group</b>	III
<b>(e)</b>	<b>Environmental Hazards</b>	Yes

**IATA:** This product is not regulated as a dangerous good when transported in sizes of  $\leq 5$  L or  $\leq 5$  kg, provided the packaging meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

**Quantity limitation** Passenger and Cargo Aircraft: 400 kg. Packaging instructions: 956. Cargo Aircraft Only: 400 kg. Packaging instructions: 956. Limited Quantities - Passenger Aircraft: 30 kg. Packaging instructions: Y956.

**Special provisions** A97, A158, A179, A197


<b>(a)</b>	<b>UN Number</b>	UN3077
<b>(b)</b>	<b>UN Proper Shipping Name</b>	Environmentally hazardous
<b>(c)</b>	<b>Transport Hazard Class(es)</b>	9
<b>(d)</b>	<b>Packing Group</b>	III
<b>(e)</b>	<b>Environmental Hazards</b>	Yes

**IMDG:** This product is not regulated as a dangerous good when transported in sizes of  $\leq 5$  L or  $\leq 5$  kg, provided the packaging meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

**Emergency schedules** F-A, S-F

**Special provisions** 274, 335, 966, 967, 969

<b>(a)</b>	<b>UN Number</b>	UN3077
<b>(b)</b>	<b>UN Proper Shipping Name</b>	Environmentally hazardous
<b>(c)</b>	<b>Transport Hazard Class(es)</b>	9
<b>(d)</b>	<b>Packing Group</b>	III
<b>(e)</b>	<b>Environmental Hazards</b>	Yes

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**Special precautions for user: Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to Annex II of MARPOL and the IBC Code:** Not available.

### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations:**

**TSCA 8(a) CDR Exempt/Partial exemption:** Not determined

**United States inventory (TSCA 8b):** Not determined.

**Clean Water Act (CWA) 311:** sodium hydroxide; Hydrochloric acid

**SARA 302/304 –**

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Hydrochloric acid	≤0.1	Yes.	500	-	5000	-

**SARA 311/312:**

**Classification:** COMBUSTIBLE DUSTS

ACUTE TOXICITY (oral) Category 4

ACUTE TOXICITY (inhalation) - Category 4

SKIN IRRITATION - Category 2


EYE IRRITATION - Category 2A

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (prostate, respiratory tract, testes) - Category 2

**Composition/information on ingredients**

Name	%	Classification
lactose	≥50 - ≤75	COMBUSTIBLE DUSTS
{3-[[[(2R,3S)-2-{{(1R)-1-[3,5-Bis(trifluoromethyl) phenyl]ethoxy}-3-(4-fluorophenyl)morpholine-4-yl] methyl]-5-oxo-4,5-dihydro-1H-1,2,4-triazole-1-yl} phosphonic acid, bis [1-deoxy-1-(methylamino)-D-glucitol] salt	≥25 - ≤50	ACUTE TOXICITY (oral) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (prostate, testes) - Category 2
Sorbitan monooleate, ethoxylated	≥10 - ≤25	EYE IRRITATION - Category 2A

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Name	%	Classification
Glycine, N,N'-1,2-ethanediylbis [N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	≤3	ACUTE TOXICITY (inhalation) - Category 4 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (respiratory tract) (inhalation) - Category 2
sodium hydroxide	≤0.1	CORROSIVE TO METALS - Category 1 ACUTE TOXICITY (dermal) - Category 4 SKIN CORROSION - Category 1A SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNOC - Corrosive to digestive tract [severe]
Hydrochloric acid	≤0.1	SKIN CORROSION - Category 1B SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNOC - Corrosive to digestive tract

**SARA 313** – Not applicable

### Section 16 - Other Information

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.


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**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice



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CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System