

# Fosaprepitant Dimeglumine for Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Fosaprepitant Dimeglumine for Injection  
Other means of identification : Single dose vial packaged individually in a carton NDC 55150-299-01

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics  
279 Princeton Highstown Road  
East Windsor, NJ 08520

#### 1.4. Emergency telephone number

Emergency number : 1-888-238-7880

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS US classification

Acute Tox. 4 (Oral) H302  
Skin Irrit. 2 H315  
Eye Irrit. 2 H319  
Comb. Dust

Full text of hazard classes, H- and EUH-statements: see section 16

#### 2.2. Label elements

##### GHS US labeling

Hazard pictograms (GHS US) :



GHS07

Signal word (GHS US) : Warning  
Hazard statements (GHS US) : May form combustible dust concentrations in air  
H302 - Harmful if swallowed  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
Precautionary statements (GHS US) : P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.  
P302+P352 - If on skin: Wash with plenty of water.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P330 - Rinse mouth.  
P332+P313 - If skin irritation occurs: Get medical advice/attention.  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

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### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
.beta.-D-Lactose	(CAS-No.) 63-42-3	> 60	Comb. Dust
Fosaprepitant Dimeglumine	(CAS-No.) 265121-04-8	> 24	Not classified
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives	(CAS-No.) 9005-65-6	> 10	Not classified
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	(CAS-No.) 6381-92-6	> 1	Not classified
Hydrochloric acid	(CAS-No.) 7647-01-0	< 1	Skin Corr. 1, H314 Eye Dam. 1, H318
Sodium hydroxide	(CAS-No.) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318

Full text of hazard classes, H- and EUH-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.

First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : None anticipated during normal product use.

Symptoms/injuries after skin contact : Causes skin irritation.

Symptoms/injuries after eye contact : Causes serious eye irritation.

Symptoms/injuries after ingestion : Harmful if swallowed.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

#### 5.3. Advice for firefighters

Protection during firefighting : During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

##### 6.1.1. For non-emergency personnel

No additional information available

##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

#### 6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

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Methods for cleaning up : Place in a suitable container and dispose according to local, state and federal regulations.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 2° to 8°C (36° to 46°F).

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
OSHA	OSHA PEL (Ceiling)	7 mg/m <sup>3</sup>
OSHA	OSHA PEL C [ppm]	5 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (Ceiling)	7 mg/m <sup>3</sup>
NIOSH	NIOSH REL C [ppm]	5 ppm
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) [1]	2 mg/m <sup>3</sup>
IDLH	IDLH	10 mg/m <sup>3</sup>
NIOSH	NIOSH REL (Ceiling)	2 mg/m <sup>3</sup>
Fosaprepitant Dimeglumine (265121-04-8)		
Not applicable		
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)		
Not applicable		
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)		
Not applicable		
.beta.-D-Lactose (63-42-3)		
Not applicable		

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : Use neoprene or rubber gloves.  
Eye protection : In case of dust production: protective goggles.  
Skin and body protection : Wear suitable working clothes.  
Respiratory protection : Wear NIOSH approved respirator when handling.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid  
Appearance : Lyophilized cake or powder  
Color : White to off-white  
Odor : Odorless  
Odor threshold : No data available  
pH : No data available  
Melting point : No data available

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Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: completely soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

Air contact.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Fosaprepitant Dimeglumine for Injection	
ATE US (oral)	500 mg/kg body weight
Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h
Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

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### Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)

LD50 oral rat	34500 µl/kg
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### .beta.-D-Lactose (63-42-3)

LD50 oral rat	> 10 g/kg
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Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

### Hydrochloric acid (7647-01-0)

IARC group	3 - Not classifiable
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Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified

STOT-repeated exposure	: Not classified
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Aspiration hazard	: Not classified
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## SECTION 12: Ecological information

### 12.1. Toxicity

#### Sodium hydroxide (1310-73-2)

LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
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### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Dispose of contents/container in accordance with local/regional/national/international regulations.
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## SECTION 14: Transport information

### Department of Transportation (DOT)

In accordance with DOT

Not applicable

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### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

##### Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory  
Listed on the United States SARA Section 302  
Subject to reporting requirements of United States SARA Section 313

CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

##### Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	1000 lb
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##### Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
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##### .beta.-D-Lactose (63-42-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### 15.2. US State regulations

##### Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List  
U.S. - Minnesota - Hazardous Substance List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

##### Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List  
U.S. - Minnesota - Hazardous Substance List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

### SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1	Skin corrosion/irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*