SAFETY DATA SHEET

Fosaprepitant Formulation

SECTION 1. IDENTIFICATION

Product name : Fosaprepitant Formulation
Other means of identification : No data available

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Acute toxicity (Oral) : Category 4
Skin irritation : Category 2
Eye irritation : Category 2A
Specific target organ toxicity - repeated exposure : Category 2 (Respiratory Tract)
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Reproductive organs, Prostate)

GHS label elements
Hazard pictograms
Signal Word : Warning
Hazard Statements :
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.
H373 May cause damage to organs (Reproductive organs, Prostate) through prolonged or repeated exposure if swallowed.

Precautionary Statements :
Prevention:
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling. 
P270 Do not eat, drink or smoke when using this product. 
P280 Wear protective gloves, eye protection and face protection. 

Response:  
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.  
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.  
P314 Get medical attention if you feel unwell.  
P332 + P313 If skin irritation occurs: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  

Disposal:  
P501 Dispose of contents and container to an approved waste disposal plant. 

Other hazards  
May form explosive dust-air mixture during processing, handling or other means. 

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS 

Substance / Mixture : Mixture 

Components 

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosaprepitant</td>
<td>No data available</td>
<td>265121-04-8</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>Ethylenediaminetetraacetic acid disodium salt dihydrate</td>
<td>6381-92-6</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret 

SECTION 4. FIRST AID MEASURES 

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice. 

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur. 

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

**In case of eye contact:**
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

**If swallowed:**
If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

**Most important symptoms and effects, both acute and delayed:**
Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure.

**Protection of first-aiders:**
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

**Notes to physician:**
Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media:**
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

**Unsuitable extinguishing media:**
None known.

**Specific hazards during firefighting:**
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

**Hazardous combustion products:**
Carbon oxides
Nitrogen oxides (NOx)
Metal oxides

**Specific extinguishing methods:**
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

**Special protective equipment for fire-fighters:**
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:**
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions:**
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Sweeping up or vacuuming up spillage and collecting in a suitable container for disposal.
- Avoid dispersing dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Do not get in eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
- Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosaprepitant</td>
<td>265121-04-8</td>
<td>TWA</td>
<td>200 µg/m³</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Particulates type
Hand protection
Material: Chemical-resistant gloves
Remarks: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Eye protection: Wear the following personal protective equipment:
Safety goggles
Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance: powder
Color: off-white
Odor: odorless
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
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Version 6.0  Revision Date: 03/20/2023  SDS Number: 23898-00022  Date of last issue: 10/01/2022  Date of first issue: 10/21/2014

Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
: May form explosive dust-air mixture during processing, handling or other means.
: Can react with strong oxidizing agents.
Conditions to avoid : Heat, flames and sparks.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1,435 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Fosaprepitant:
Acute oral toxicity: LD50 (Rat, female): > 500 mg/kg
LD50 (Mouse, female): > 500 mg/kg

Disodium EDTA, dihydrate:
Acute oral toxicity: LD50 (Rat): 2,800 mg/kg

Acute inhalation toxicity: LC50 (Rat, male): > 1 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 412

Skin corrosion/irritation
Causes skin irritation.

Components:

Fosaprepitant:
Species: Rabbit
Result: Skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.
Components:

Fosaprepitant:

<table>
<thead>
<tr>
<th>Species</th>
<th>Bovine cornea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Eye irritation</td>
</tr>
</tbody>
</table>

Disodium EDTA, dihydrate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Disodium EDTA, dihydrate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Fosaprepitant:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: human lymphoblastoid cells</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

|                        | Test Type: sister chromatid exchange assay           |
|                        | Test system: Chinese hamster ovary cells            |
|                        | Result: negative                                     |

|                       | Test Type: in vitro test                            |
|                       | Test system: rat hepatocytes                         |
|                       | Result: negative                                     |

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: In vivo micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Disodium EDTA, dihydrate:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
</table>
SAFETY DATA SHEET
Fosaprepitant Formulation

Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Carcinogenicity
Not classified based on available information.

Components:
Fosaprepitant:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td></td>
<td>50 mg/kg body weight</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>Benign tumor(s)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td></td>
<td>250 mg/kg body weight</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, Thyroid</td>
</tr>
</tbody>
</table>

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

Disodium EDTA, dihydrate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Reproductive toxicity
Not classified based on available information.

Components:
Fosaprepitant:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat, male and female</td>
</tr>
</tbody>
</table>
### Fosaprepitant Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>03/20/2023</td>
<td>23898-00022</td>
<td>10/01/2022</td>
<td>10/21/2014</td>
</tr>
</tbody>
</table>

#### Fertility
- NOAEL: 2,000 mg/kg body weight
- Result: negative

#### Effects on fetal development
- Species: Rat, female
- General Toxicity Maternal: NOAEL: 2,000 mg/kg body weight
- Result: negative
- Species: Rabbit, female
- General Toxicity Maternal: NOAEL: 25 mg/kg body weight
- Result: negative

**Disodium EDTA, dihydrate**

#### Effects on fertility
- Test Type: Four-generation reproduction toxicity study
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

#### Effects on fetal development
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

**STOT-single exposure**
Not classified based on available information.

**STOT-repeated exposure**
May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.
May cause damage to organs (Reproductive organs, Prostate) through prolonged or repeated exposure if swallowed.

**Components:**

**Fosaprepitant:**
- Routes of exposure: Ingestion
- Target Organs: Reproductive organs, Prostate
- Assessment: May cause damage to organs through prolonged or repeated exposure.

**Disodium EDTA, dihydrate:**
- Routes of exposure: Inhalation (dust/mist/fume)
- Target Organs: Respiratory Tract
- Assessment: May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Fosaprepitant:**
- Species: Rat, male and female
- NOAEL: 2,000 mg/kg
- Application Route: Oral
Exposure time: 6 Months
Target Organs: Liver, Thyroid

Species: Dog
LOAEL: 50 mg/kg
Application Route: Oral
Exposure time: 9 Months
Target Organs: Testis

Species: Dog
NOAEL: 32 mg/kg
Application Route: Oral
Exposure time: 1 year
Remarks: No significant adverse effects were reported

Species: Rat
NOAEL: 4 mg/kg
Application Route: Intravenous
Exposure time: 5 Weeks
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 10 mg/kg
Application Route: Intravenous
Exposure time: 5 Weeks
Remarks: No significant adverse effects were reported

Disodium EDTA, dihydrate:
Species: Rat
NOAEL: 500 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks

Species: Rat
LOAEL: 0.03 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 4 Weeks
Method: OECD Test Guideline 412

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Fosaprepitant:
Ingestion: Symptoms: hiccups, Fatigue, liver function change, constipation, Headache, anorexia
## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

**Components:**

**Fosaprepitant:**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow)): &gt; 0.462 mg/l</td>
<td>OECD Test Guideline 203</td>
<td>No toxicity at the limit of solubility. Based on data from similar materials</td>
</tr>
<tr>
<td>Exposure time</td>
<td>96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 0.345 mg/l</td>
<td>OECD Test Guideline 202</td>
<td>No toxicity at the limit of solubility. Based on data from similar materials</td>
</tr>
<tr>
<td>Exposure time</td>
<td>48 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.184 mg/l</td>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility. Based on data from similar materials</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.195 mg/l</td>
<td>OECD Test Guideline 210</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Exposure time</td>
<td>32 Days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 0.018 mg/l</td>
<td>OECD Test Guideline 211</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Exposure time</td>
<td>21 Days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Disodium EDTA, dihydrate:**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Lepomis macrochirus (Bluegill sunfish)): &gt; 100 mg/l</td>
<td></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Exposure time</td>
<td>96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 140 mg/l</td>
<td>DIN 38412</td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>48 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Persistence and degradability

#### Components:

**Fosaprepitant:**
- **Biodegradability**: Result: not rapidly degradable
- Method: OECD Test Guideline 314

**Disodium EDTA, dihydrate:**
- **Biodegradability**: Result: Not readily biodegradable.
  - Biodegradation: 2 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301D

#### Bioaccumulative potential

#### Components:

**Fosaprepitant:**
- **Bioaccumulation**: Species: Lepomis macrochirus (Bluegill sunfish)
  - Bioconcentration factor (BCF): 50.1
  - Method: OECD Test Guideline 305
  - Remarks: Based on data from similar materials

**Disodium EDTA, dihydrate:**
- **Bioaccumulation**: Species: Lepomis macrochirus (Bluegill sunfish)
  - Bioconcentration factor (BCF): < 500
  - Remarks: Based on data from similar materials

- **Partition coefficient: n-octanol/water**: log Pow: -4.3

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **NOEC (Daphnia magna (Water flea))**: 25 mg/l
  - Exposure time: 21 d

### Toxicity to microorganisms
- **EC10 (activated sludge)**: > 500 mg/l
  - Exposure time: 30 min
  - Method: OECD Test Guideline 209

### Exposition time:
- 72 h
- Method: OECD Test Guideline 201

### Remarks:
- Based on data from similar materials

### Exposure time:
- 72 h
- Method: OECD Test Guideline 201

### Remarks:
- Based on data from similar materials

### EC10 (Pseudokirchneriella subcapitata (green algae))
- > 1 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

### Remarks:
- Based on data from similar materials
Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
  Do not dispose of waste into sewer.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
  If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fosaprepitant)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Fosaprepitant)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fosaprepitant)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
UN number : UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fosaprepitant)

Class: 9

Packing group: III

Labels: 9

ERG Code: 171

Marine pollutant: yes (Fosaprepitant)

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation,
SAFETY DATA SHEET

Fosaprepitant Formulation

Version 6.0  Revision Date: 03/20/2023  SDS Number: 23898-00022  Date of last issue: 10/01/2022

Date of first issue: 10/21/2014

Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 03/20/2023
Date format: mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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