SAFETY DATA SHEET

Fosaprepitant Formulation

SECTION 1. IDENTIFICATION

Product name: Fosaprepitant Formulation

Manufacturer or supplier's details

Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
 Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

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:
If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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/ face protection.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of soap and 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 advice/ attention if you feel unwell.
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.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosaprepitant</td>
<td>Mixture</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosaprepitant</td>
<td>265121-04-8</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration 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 fire fighting:
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 and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided. 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:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of 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.
- 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.
- 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). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

**Personal protective equipment**

**Respiratory protection**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

---
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
<td>off-white</td>
</tr>
<tr>
<td>Odor</td>
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<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
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<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
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<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
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<tr>
<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
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<tr>
<td>Upper explosion limit / Upper flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<tr>
<td>Vapor pressure</td>
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<td>Relative vapor density</td>
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<tr>
<td>Solubility(ies)</td>
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<td>Water solubility</td>
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<tr>
<td>Decomposition temperature</td>
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<td>Viscosity, dynamic</td>
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<td>Viscosity, kinematic</td>
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<td>Explosive properties</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
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<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Fosaprepitant Formulation

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: 38.85 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
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 1 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 412
Remarks: Based on data from similar materials
Skin corrosion/irritation
Causes skin irritation.

Components:
Fosaprepitant:
Species: Rabbit
Result: Skin irritation

Disodium EDTA, dihydrate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:
Fosaprepitant:
Species: Bovine cornea
Result: Eye irritation

Disodium EDTA, dihydrate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Disodium EDTA, dihydrate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:
Fosaprepitant:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Test system: human lymphoblastoid cells
Result: negative

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

Genotoxicity in vivo:
Test Type: In vivo micronucleus test
Species: Mouse
Cell type: Bone marrow
Result: negative

Disodium EDTA, dihydrate:
Genotoxicity in vitro:
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
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:

Fosaprepitant:
Species: Rat, female
Application Route: Oral
Exposure time: 2 Years
: 50 mg/kg body weight
Target Organs: Liver
Remarks: Benign tumor(s)

Species: Rat, male and female
Application Route: Oral
Exposure time: 2 Years
: 250 mg/kg body weight
Target Organs: Liver, Thyroid

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

Disodium EDTA, dihydrate:
Species: Rat
Application Route: Ingestion
Exposure time: 103 weeks
Result: negative
Remarks: Based on data from similar materials

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:

**Fosaprepitant:**
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, male and female
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
Remarks: Based on data from similar materials

**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 : Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d.

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 y
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
Remarks: Based on data from similar materials

Species: Rat
LOAEL: 0.03 mg/l

Application Route: inhalation (dust/mist/fume)
Exposure time: 4 Weeks
Remarks: Based on data from similar materials

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:

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 0.462 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility.
Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 0.345 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.
Based on data from similar materials

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 0.184 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.
Based on data from similar materials

EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.184 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.
Based on data from similar materials

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.195 mg/l
Exposure time: 32 Days
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- NOEC (Daphnia magna (Water flea)): 0.018 mg/l
- Exposure time: 21 Days
- Method: OECD Test Guideline 211
- Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:

Toxicity to fish

- LC50 (Lepomis macrochirus (Bluegill sunfish)): 159 mg/l
- Exposure time: 96 h
- Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates

- EC50 (Daphnia magna (Water flea)): 140 mg/l
- Exposure time: 48 h
- Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants

- EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
- Exposure time: 72 h
- Remarks: Based on data from similar materials

- NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l
- Exposure time: 72 h
- Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity)

- NOEC (Danio rerio (zebra fish)): 25.7 mg/l
- Exposure time: 35 d
- Method: OECD Test Guideline 210
- Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- NOEC (Daphnia magna (Water flea)): 25 mg/l
- Exposure time: 21 d
- Remarks: Based on data from similar materials

Toxicity to microorganisms

- EC50: < 500 mg/l
- Exposure time: 0.5 h
- Method: OECD Test Guideline 209
- Remarks: Based on data from similar materials

Persistence and degradability

Components:

Fosaprepitant:

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

Disodium EDTA, dihydrate:

- Biodegradability: Result: Inherently biodegradable.
- Biodegradation: 80 - 90 %
- Exposure time: 28 d
- Remarks: Based on data from similar materials
## 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): 1.8
  - Remarks: Based on data from similar materials
- **Partition coefficient: n-octanol/water**
  - log Pow: -4.3

**Mobility in soil**
- No data available

**Other adverse effects**
- No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

- **Waste from residues:** Dispose of in accordance with local regulations.
- **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 (passen-**

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SAFETY DATA SHEET

Fosaprepitant Formulation

Version 9.1
Revision Date: 09/13/2019
SDS Number: 23926-00014
Date of last issue: 04/24/2019
Date of first issue: 10/21/2014

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

49 CFR
UN/ID/NA number: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Fosaprepitant)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Fosaprepitant)
Remarks: Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

EPCRA - Emergency Planning and Community Right-to-Know
CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
Combustible dust
Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation
Specific target organ toxicity (single or repeated exposure)

**SARA 313**

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

**Pennsylvania Right To Know**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
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<tr>
<td>Fosaprepitant</td>
<td>265121-04-8</td>
</tr>
<tr>
<td>Polyethylene glycol sorbitan monooleate</td>
<td>9005-65-6</td>
</tr>
</tbody>
</table>

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

**SECTION 16. OTHER INFORMATION**

**Further information**

**NFPA 704:**

- Flammability
  - Health: 1
  - Physical Hazard: 0
  - Special Hazard

**HMIS® IV:**

- **HEALTH**: * 2
- **FLAMMABILITY**: 3
- **PHYSICAL HAZARD**: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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 Sys-
SAFETY DATA SHEET

Fosaprepitant Formulation

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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/13/2019

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