SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Fosaprepitant Formulation

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
Company: MSD
Piercetown
A86 HD21 Dunboyne, Ireland
Telephone: 908-740-4000
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 4: H302: Harmful if swallowed.
Skin irritation, Category 2: H315: Causes skin irritation.
Eye irritation, Category 2: H319: Causes serious eye irritation.
Specific target organ toxicity - repeated exposure, Category 2: H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
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 through prolonged or repeated exposure.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P260  Do not breathe dust.
P273  Avoid release to the environment.
P280  Wear protective gloves/ eye protection/ face protection.

Response:
P314  Get medical advice/ attention if you feel unwell.
P337 + P313  If eye irritation persists: Get medical advice/ attention.
P391  Collect spillage.

Hazardous components which must be listed on the label:
Fosaprepitant

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosaprepitant</td>
<td>265121-04-8</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT RE 2; H373 (Reproductive organs, Prostate) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>
Fosaprepitant Formulation

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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).

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

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.
SECTION 5: Firefighting measures

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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

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

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.

SECTION 6: Accidental release measures

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

6.2 Environmental precautions
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.

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

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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.

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers:
Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s):
No data available
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameter</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>

8.2 Exposure controls

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

Eye protection: Wear the following personal protective equipment:
Safety goggles
Equipment should conform to I.S. EN 166

Hand protection

Material: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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.

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).

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<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>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
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</tr>
<tr>
<td>Viscosity, dynamic</td>
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<tr>
<td>Viscosity, kinematic</td>
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<tr>
<td>Solubility (ies)</td>
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<tr>
<td>Water solubility</td>
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<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
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<tr>
<td>Vapour pressure</td>
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<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2 Other information

Explosives: Not explosive
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1,454 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
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 sensitisation
Skin sensitisation
Not classified based on available information.
### Respiratory sensitisation
Not classified based on available information.

**Components:**

**Disodium EDTA, dihydrate:**
- **Test Type**: Maximisation Test  
- **Exposure routes**: 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 assay  
  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
Target Organs: Liver
Remarks: Benign tumor(s)

Species: Rat, male and female
Application Route: Oral
Exposure time: 2 Years
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

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 foetal 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 foetal development:
Test Type: Embryo-foetal 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 through prolonged or repeated exposure.

Components:
Fosaprepitant:
Exposure routes: Ingestion
Target Organs: Reproductive organs, Prostate
Assessment: May cause damage to organs through prolonged or repeated exposure.

Disodium EDTA, dihydrate:
Exposure routes: 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 yr
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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Fosaprepitant:
Ingestion: Symptoms: hiccups, Fatigue, liver function change, constipation, Headache, anorexia

SECTION 12: Ecological information

12.1 Toxicity

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
NOEC: 0.018 mg/l
Exposure time: 21 Days
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity): 1

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 25 mg/l
   Exposure time: 21 d
   Species: Daphnia magna (Water flea)
   Remarks: Based on data from similar materials

12.2 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

12.3 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

12.4 Mobility in soil
   No data available
12.5 Results of PBT and vPvB assessment

**Product:**
**Assessment:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
**Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

14.1 UN number or ID number

**ADN** : UN 3077

**ADR** : UN 3077

**RID** : UN 3077

**IMDG** : UN 3077

**IATA** : UN 3077

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fosaprepitant)

**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fosaprepitant)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fosaprepitant)

IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fosaprepitant)

IATA: Environmentally hazardous substance, solid, n.o.s. (Fosaprepitant)

14.3 Transport hazard class(es)

ADN: 9
ADR: 9
RID: 9
IMDG: 9
IATA: 9

14.4 Packing group

ADN
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9

ADR
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9
Tunnel restriction code: (-)

RID
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9

IMDG
Packing group: III
Labels: 9
EmS Code: F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft): 956
Packing instruction (LQ): Y956
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fosaprepitant Formulation

Version: 3.6
Revision Date: 27.08.2021
SDS Number: 23911-00018
Date of last issue: 09.04.2021
Date of first issue: 21.10.2014

Packing group: III
Labels: Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

REACH - List of substances subject to authorisation (Annex XIV): Not applicable


<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

**The components of this product are reported in the following inventories:**

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

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

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

**Full text of H-statements**

- **H302**: Harmful if swallowed.
- **H315**: Causes skin irritation.
- **H319**: Causes serious eye irritation.
- **H332**: Harmful if inhaled.
- **H373**: May cause damage to organs through prolonged or repeated exposure.
- **H373**: May cause damage to organs through prolonged or repeated exposure if swallowed.
- **H410**: Very toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

- **Acute Tox.**: Acute toxicity
- **Aquatic Chronic**: Long-term (chronic) aquatic hazard
- **Eye Irrit.**: Eye irritation
- **Skin Irrit.**: Skin irritation
- **STOT RE**: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Stand-
Fosaprepitant Formulation

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Further information

Classification of the mixture:

<table>
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<tr>
<th>Classification</th>
<th>Code</th>
<th>Notes</th>
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<tr>
<td>Acute Tox. 4</td>
<td>H302</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
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</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
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<tr>
<td>STOT RE 2</td>
<td>H373</td>
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</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
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