

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Fosaprepitant Formulation

Version 5.1      Revision Date: 26.09.2023      SDS Number: 23911-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

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### 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 Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

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

Company : MSD  
Innishannon  
County Cork - Ireland

Telephone : 353 214329300

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

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### 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 :



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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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Fosaprepitant	265121-04-8	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT RE 2; H373 (Reproductive or-	>= 30 - < 50

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		gans, Prostate) Aquatic Chronic 1; H410	
		M-Factor (Chronic aquatic toxicity): 1	
Disodium EDTA, dihydrate	6381-92-6	Acute Tox. 4; H332 STOT RE 2; H373 (Respiratory Tract)	>= 1 - < 10

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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.
- 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.

#### 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

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exposure.

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

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

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 (NO<sub>x</sub>)  
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.

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## 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.

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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.

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## 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 : Keep in properly labelled containers. Store in accordance with

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areas and containers      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

dusts non-specific      4 mg/m<sup>3</sup>  
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)  
Basis: IE OEL

10 mg/m<sup>3</sup>  
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)  
Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Fosaprepitant	265121-04-8	TWA	200 µg/m <sup>3</sup>	Internal

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Disodium EDTA, dihydrate	Workers	Inhalation	Long-term systemic effects	1.5 mg/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	3 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term local effects	1.5 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	3 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	0.6 mg/m <sup>3</sup>
	Consumers	Inhalation	Acute local effects	1.2 mg/m <sup>3</sup>
	Consumers	Ingestion	Long-term systemic effects	25 mg/kg bw/day

#### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Disodium EDTA, dihydrate	Fresh water	2.5 mg/l
	Marine water	0.25 mg/l
	Sewage treatment plant	50 mg/l

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	Soil	1.1 mg/kg dry weight (d.w.)
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### 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/face 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

Physical state : powder  
Colour : off-white  
Odour : odourless  
Odour Threshold : No data available

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Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Relative vapour density	:	No data available
Particle characteristics		
Particle size	:	No data available

### 9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.



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Evaporation rate : No data available

Molecular weight : No data available

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### 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.

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### SECTION 11: Toxicological information

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

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1,454 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:**

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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:**

Species : Bovine cornea  
Result : Eye irritation

### **Disodium EDTA, dihydrate:**

Species : Rabbit  
Result : No eye irritation

### **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  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

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### 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: Bacterial reverse mutation assay (AMES)  
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:**

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

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Target Organs : 50 mg/kg body weight  
                  : 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

### 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

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### 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 : 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 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

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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.

## 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

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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: 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)): > 100 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

Method: DIN 38412

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l

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

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

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

### 12.2 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

### 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): < 500  
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.



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### 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

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## 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. 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.

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## 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.

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

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	: 9	
<b>ADR</b>	: 9	
<b>RID</b>	: 9	
<b>IMDG</b>	: 9	
<b>IATA</b>	: 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  
Packing group : III  
Labels : Miscellaneous

### 14.5 Environmental hazards

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### 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, mixtures and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national

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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.

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## 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
IE OEL	:	List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	:	Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIC - 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 - Interna-

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tional 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Acute Tox. 4	H302
Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT RE 2	H373
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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.

IE / EN