

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version 12.0      Revision Date: 06.12.2025      SDS Number: 23923-00024      Date of last issue: 14.04.2025  
Date of first issue: 21.10.2014

### SECTION 1. IDENTIFICATION

Product name : Fosaprepitant Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : Pridco Industrial Park, Rd. 183  
Las Piedras, PR 00771  
Telephone : 787-912-2222  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

##### Hazards for the product as supplied

Acute toxicity (Oral) : Category 4  
Skin irritation : Category 2  
Eye irritation : Category 2A  
Specific target organ toxicity : Category 2 (Respiratory Tract)  
- repeated exposure  
Specific target organ toxicity : Category 2 (Reproductive organs, Prostate)  
- repeated exposure (Oral)

##### Other hazards

None known.

##### Hazards associated with a change in physical form:

Conditions	Hazards
If small particles are generated during further processing, handling or by other means.	May form combustible dust concentrations in air.

##### GHS label elements

Hazard pictograms :  

Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version 12.0      Revision Date: 06.12.2025      SDS Number: 23923-00024      Date of last issue: 14.04.2025  
Date of first issue: 21.10.2014

H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.  
H373 May cause damage to organs (Reproductive organs, Prostate) through prolonged or repeated exposure if swallowed.

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

**Response:**  
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.  
P302 + P352 IF ON SKIN: Wash with plenty of water.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P314 Get medical attention if you feel unwell.  
P332 + P313 If skin irritation occurs: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Fosaprepitant	265121-04-8*	$\geq 15 - \leq 40$	TSC
Disodium EDTA, dihydrate	6381-92-6*	$\geq 1 - \leq 5$	TSC

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

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. No information available.
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 (CO <sub>2</sub> ) 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 (NO <sub>x</sub> ) 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

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

### SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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

Methods and materials for containment and cleaning up : 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.  
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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

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

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	15 mg/m <sup>3</sup> Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	5 mg/m <sup>3</sup> Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
	15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
Dust, nuisance dust and particulates	10 mg/m <sup>3</sup> Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL
	5 mg/m <sup>3</sup> Value type (Form of exposure): PEL (respirable dust fraction) Basis: CAL PEL

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

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.  
Apply measures to prevent dust explosions.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

#### Personal protective equipment

Respiratory protection : 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version 12.0	Revision Date: 06.12.2025	SDS Number: 23923-00024	Date of last issue: 14.04.2025 Date of first issue: 21.10.2014
-----------------	------------------------------	----------------------------	---

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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : off-white

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

	handling or other means.
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics	
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. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition	: No hazardous decomposition products are known.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

products

### 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: 57,69 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

#### Components:

##### Fosaprepitant:

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

##### Disodium EDTA, dihydrate:

Acute oral toxicity	:	LD50 (Rat): 2.800 mg/kg
Acute inhalation toxicity	:	LC50 (Rat, male): > 1 mg/l Exposure time: 6 h Test atmosphere: dust/mist Method: OECD Test Guideline 412

#### Skin corrosion/irritation

Causes skin irritation.

#### Components:

##### Fosaprepitant:

Species	:	Rabbit
Result	:	Skin irritation

#### Serious eye damage/eye irritation

Causes serious eye irritation.



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

### Components:

#### **Fosaprepitant:**

Species	: Bovine cornea
Result	: Eye irritation

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

Species	: Rabbit
Result	: No eye irritation

### **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
Method	: OECD Test Guideline 406
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:**

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

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
	: 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

**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

### 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)
--------------------	-------------------------------

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

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 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

Species	: Rat
LOAEL	: 0,03 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 4 Weeks
Method	: OECD Test Guideline 412

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

### Disodium EDTA, dihydrate:

- |  |   |   |
|--|---|---|
| Toxicity to fish   | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials   |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia magna (Water flea)): 140 mg/l<br>Exposure time: 48 h<br>Method: DIN 38412   |
| Toxicity to algae/aquatic plants                                       | : | ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials<br><br>EC10 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 25 mg/l<br>Exposure time: 21 d   |
| Toxicity to microorganisms   | : | EC10 (activated sludge): > 500 mg/l<br>Exposure time: 30 min<br>Method: OECD Test Guideline 209   |

### Persistence and degradability

#### Components:

##### Fosaprepitant:

- |                  |   |   |
|------------------|---|---|
| Biodegradability | : | Result: not rapidly degradable<br>Method: OECD Test Guideline 314 |
|------------------|---|---|

##### Disodium EDTA, dihydrate:

- |                  |   |  |
|------------------|---|--|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 2 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301D |
|------------------|---|--|

### Bioaccumulative potential

#### Components:

##### Fosaprepitant:

- |                 |   |  |
|-----------------|---|--|
| Bioaccumulation | : | Species: Lepomis macrochirus (Bluegill sunfish)<br>Bioconcentration factor (BCF): 50,1<br>Method: OECD Test Guideline 305<br>Remarks: Based on data from similar materials |
|-----------------|---|--|

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

### 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

### 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.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

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

Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Fosaprepitant)

Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

#### IMDG-Code

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

	(Fosaprepitant)
Class	: 9
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
Marine pollutant	: yes

### Transport in bulk according to IMO instruments

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 (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. 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

### 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	: Acute toxicity (any route of exposure) Specific target organ toxicity (single or repeated exposure) Skin corrosion or irritation Serious eye damage or eye irritation
----------------------	--

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.
----------	---



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

### US State Regulations

#### Pennsylvania Right To Know

Lactose	63-42-3
Fosaprepitant	265121-04-8
Polyethylene glycol sorbitan monooleate	9005-65-6

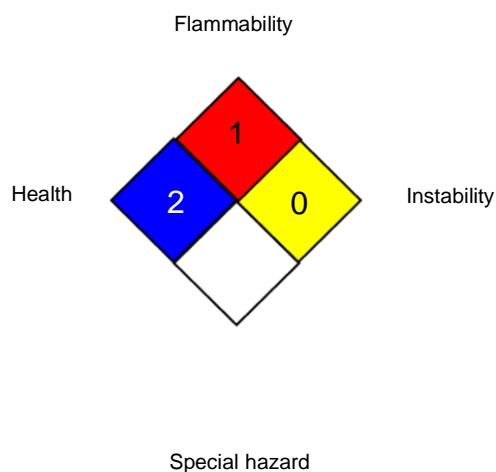
#### The ingredients of this product are reported in the following inventories:

AICS	: not determined
CA. DSL	: not determined
IECSC	: not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### 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

CAL PEL	: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3	: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
CAL PEL / PEL	: Permissible exposure limit
OSHA Z-3 / TWA	: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; 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 Standardization; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Haz-

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
12.0	06.12.2025	23923-00024	Date of first issue: 21.10.2014

ardous 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 System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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 Organization 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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

Revision Date : 06.12.2025

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

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

US / Z8