

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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
120 Moorgate
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

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) as amended by GB-CLP Regulation, UK
SI 2019/720, and UK SI 2020/1567)**

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 pro- longed or repeated exposure.
Long-term (chronic) aquatic hazard, Cat- egory 1	H410: Very toxic to aquatic life with long lasting effects.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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.
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	>= 30 - < 50

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version 4.4 Revision Date: 14.04.2025 SDS Number: 9371251-00009 Date of last issue: 28.09.2024
Date of first issue: 27.08.2021

		Eye Irrit. 2; H319 STOT RE 2; H373 (Reproductive or- gans, Prostate) Aquatic Chronic 1; H410	
		M-Factor (Chronic aquatic toxicity): 1	
Disodium EDTA, dihydrate	6381-92-6 205-358-3	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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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 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_x)
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).

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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 contami-

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version 4.4 Revision Date: 14.04.2025 SDS Number: 9371251-00009 Date of last issue: 28.09.2024
Date of first issue: 27.08.2021

nated 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

dust of any kind 10 mg/m³
Value type (Form of exposure): TWA (Inhalable)
Basis: GB EH40

4 mg/m³
Value type (Form of exposure): TWA (Respirable fraction)
Basis: GB EH40

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

Derived No Effect Level (DNEL)

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

Predicted No Effect Concentration (PNEC)

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

	Sewage treatment plant	50 mg/l
	Soil	1.1 mg/kg dry weight (d.w.)

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 BS 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 BS EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	off-white
Odour	:	odourless
Odour Threshold	:	No data available
pH	:	No data available

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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, 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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition 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.

9.2 Other information

Molecular weight	:	No data available
Particle size	:	No data available

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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 toxicological effects

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:

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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

Germ cell mutagenicity

Not classified based on available information.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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
: 50 mg/kg body weight
Target Organs : Liver
Remarks : Benign tumor(s)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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

STOT - single exposure

Not classified based on available information.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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
Exposure time	: 5 Weeks
Remarks	: No significant adverse effects were reported

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

Disodium EDTA, dihydrate:

Species	:	Rat
NOAEL	:	500 mg/kg
Application Route	:	Ingestion
Exposure time	:	13 Weeks

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Fosaprepitant:

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

SECTION 12: Ecological information

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
----------------------------------	---	---

EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.184 mg/l
Exposure time: 72 h

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

		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
Toxicity to microorganisms	:	EC10 (activated sludge): > 500 mg/l Exposure time: 30 min Method: OECD Test Guideline 209
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 25 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

12.2 Persistence and degradability

Components:

Fosaprepitant:

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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 han-
dling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN 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)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN	
Packing group	: III

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable	
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable	
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable	
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable	
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable	
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable	
Control of Major Accident Hazards Regulations 2015 (COMAH)	:	Not applicable	
E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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
GB EH40	: UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	: Long-term exposure limit (8-hour TWA 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; 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 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; 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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.4	14.04.2025	9371251-00009	Date of first issue: 27.08.2021

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.

GB / EN