

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
 Date of first issue: 21.10.2014

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
 117 16th Road
 1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

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

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :   

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
 Date of first issue: 21.10.2014

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 Eye Irrit. 2; H319 STOT RE 2; H373 (Reproductive organs, Prostate) Aquatic Chronic 1; H410	>= 30 - < 50
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.

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
Date of first issue: 21.10.2014

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 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

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

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).

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
 Date of first issue: 21.10.2014

certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.
 Do not breathe dust.
 Do not swallow.
 Do not get in eyes.
 Wash skin thoroughly after handling.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Minimize dust generation and accumulation.
 Keep container closed when not in use.
 Keep away from heat and sources of ignition.
 Take precautionary measures against static discharges.
 Do not eat, drink or smoke when using this product.
 Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:
 Strong oxidizing agents

7.3 Specific end use(s)

- Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

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

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
 Date of first issue: 21.10.2014

	8		
--	---	--	--

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 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) 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
	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

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 re-

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

sistance 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.
 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
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.
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

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

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

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
Date of first issue: 21.10.2014

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:**Fosaprepitant:**

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

Disodium EDTA, dihydrate:

Acute oral toxicity : LD50 (Rat): 2.800 mg/kg
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:**

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
Date of first issue: 21.10.2014

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.

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.

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

ment

Species: Rat
Application Route: Ingestion
Result: negative

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

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

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

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

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

- 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
- 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)

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
Date of first issue: 21.10.2014

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.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : 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.

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

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.

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 | |

Fosaprepitant Formulation

Version 5.1 Revision Date: 26.09.2023 SDS Number: 23927-00023 Date of last issue: 20.03.2023
Date of first issue: 21.10.2014

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**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

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

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 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

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

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

Full text of other abbreviations

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

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

Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014

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

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.

ZA / EN

SAFETY DATA SHEET



Fosaprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	23927-00023	Date of first issue: 21.10.2014
