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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 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- : Pl

stance/Mixture

: Pharmaceutical

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

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 H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

egory 1 effects.

#### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms





Signal word : Warning

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



## Fosaprepitant Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

Hazard statements : H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H373 May cause damage to organs through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

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

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Fosaprepitant

#### 2.3 Other hazards

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

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

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

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

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

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

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



## **Fosaprepitant Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	23920-00025	Date of first issue: 21.10.2014

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

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

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 prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Metal oxides

5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective 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.

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



## Fosaprepitant Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

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 con-

tainer 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 deter-

mine 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 as-

sessment

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-

nated clothing before re-use.

#### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage : Keep in properly labelled containers. Store in accordance with

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

areas and containers the particular national regulations.

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

Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

#### **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

#### **Occupational Exposure Limits**

Dust 5 mg/m3

Value type (Form of exposure): TWA (respirable dust)

Basis: FOR-2011-12-06-1358

10 mg/m3

Value type (Form of exposure): TWA (total dust)

Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Fosaprepitant	265121-04- 8	TWA	200 μg/m3	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Disodium EDTA, di- hydrate	Workers	Inhalation	Long-term systemic effects	1,5 mg/m3
	Workers	Inhalation	Acute systemic effects	3 mg/m3
	Workers	Inhalation	Long-term local ef- fects	1,5 mg/m3
	Workers	Inhalation	Acute local effects	3 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	0,6 mg/m3
	Consumers	Inhalation	Acute local effects	1,2 mg/m3
	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.)

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

#### 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 duct

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 NS 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 re-

sistance data and an assessment of the local exposure poten-

tial.

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 143

Filter type : Particulates type (P)

#### **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : off-white

Odour : odourless

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling : No data available

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



## **Fosaprepitant Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.3
 28.09.2024
 23920-00025
 Date of first issue: 21.10.2014

range

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

dling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Relative density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

#### **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, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## **SECTION 11: Toxicological information**

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

Information on likely routes of : Inhalation

exposure 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

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

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

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

Fosaprepitant:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Test system: human lymphoblastoid cells

Result: negative

Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Result: negative

Test Type: in vitro assay Test system: rat hepatocytes

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse

Cell type: Bone marrow

Result: negative

Disodium EDTA, dihydrate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Method: OECD Test Guideline 474

Result: negative

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

Fosaprepitant:

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

: 50 mg/kg body weight

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

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 - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

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 develop-

ment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

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



## Fosaprepitant Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### Components:

Fosaprepitant:

Exposure routes : Ingestion

Target Organs : Reproductive organs, Prostate

Assessment : May cause damage to organs through prolonged or repeated

exposure.

**Disodium EDTA, dihydrate:** 

Exposure routes : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

Assessment : May cause damage to organs through prolonged or repeated

exposure.

#### Repeated dose toxicity

## **Components:**

Fosaprepitant:

Species : Rat, male and female

NOAEL : 2.000 mg/kg

Application Route : Oral
Exposure time : 6 Months
Target Organs : Liver, Thyroid

Species : Dog
LOAEL : 50 mg/kg
Application Route : Oral
Exposure time : 9 Months
Target Organs : Testis

Species : Dog
NOAEL : 32 mg/kg
Application Route : Oral
Exposure time : 1 yr

Remarks : No significant adverse effects were reported

Species : Rat

NOAEL : 4 mg/kg

Application Route : Intravenous

Exposure time : 5 Weeks

Remarks : No significant adverse effects were reported

Species : Dog NOAEL : 10 mg/kg Application Route : Intravenous

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

Exposure time : 5 Weeks

Remarks : No significant adverse effects were reported

Disodium EDTA, dihydrate:

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

Species : Rat LOAEL : 0,03 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 4 Weeks

Method : OECD Test Guideline 412

**Aspiration toxicity** 

Not classified based on available information.

11.2 Information on other hazards

**Endocrine disrupting properties** 

**Product:** 

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

**Experience with human exposure** 

**Components:** 

Fosaprepitant:

Ingestion : Symptoms: hiccups, Fatigue, liver function change, constipa-

tion, 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

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



## Fosaprepitant Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.3
 28.09.2024
 23920-00025
 Date of first issue: 21.10.2014

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 tox-

icity)

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 (Chron-

ic 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

Metriod. Dire 30412

ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 1

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

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 (Chron-

NOEC: 25 mg/l Exposure time: 21 d

ic toxicity) Species: Daphnia magna (Water flea)

12.2 Persistence and degradability

**Components:** 

Fosaprepitant:

Biodegradability : Result: not rapidly degradable

Method: OECD Test Guideline 314

Disodium EDTA, dihydrate:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 2 % Exposure time: 28 d

Method: OECD Test Guideline 301D

12.3 Bioaccumulative potential

**Components:** 

Fosaprepitant:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 50,1 Method: OECD Test Guideline 305

Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): < 500

Remarks: Based on data from similar materials

Partition coefficient: n-

octanol/water

log Pow: -4,3

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

#### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

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 or ID number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

#### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Fosaprepitant)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Fosaprepitant)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Fosaprepitant)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

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
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 : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

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



## Fosaprepitant Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

#### 14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

#### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

Not applicable

Not applicable

REACH - Restrictions on the manufacture, placing on :

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

laver

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

#### Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of

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



## Fosaprepitant Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

children and young people.

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

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

FOR-2011-12-06-1358 / : Long term exposure limit

**TWA** 

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

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



## **Fosaprepitant Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.3 28.09.2024 23920-00025 Date of first issue: 21.10.2014

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:

# Classification procedure: Calculation method

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

NO / EN