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



# **Ramipril Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 9374091-00008 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 Ramipril Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-: Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company **MSD** 

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone +1-908-740-4000

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)

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction. Reproductive toxicity, Category 1A H360D: May damage the unborn child. Specific target organ toxicity - repeated

exposure, Category 2

2.2 Label elements

H373: May cause damage to organs through pro-

longed or repeated exposure.

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

Hazard pictograms





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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H360D May damage the unborn child.

H373 May cause damage to organs through prolonged

or repeated exposure.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P272 Contaminated work clothing should not be allowed

out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical

advice/ attention.

Hazardous components which must be listed on the label:

Ramipril

Natural Pork Flavor

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment:  $10\,\%$ 

#### 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.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

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)
Ramipril	87333-19-5	Repr. 1A; H360D STOT RE 2; H373 (Kidney)	>= 10 - < 20
Hydrolyzed Vegetable Protein	Not Assigned		>= 1 - < 10
Natural Pork Flavor	Not Assigned	Skin Sens. 1B; H317	>= 1 - < 10

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

Hydrogenated Vegetable Oil	Not Assigned		>= 1 - < 10		
Substances with a workplace exposure limit :					
Starch	9005-25-8		>= 30 - < 50		
	232-679-6				
Cellulose	9004-34-6		>= 30 - < 50		
	232-674-9				

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.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

## 4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause an allergic skin reaction.

May damage the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

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

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

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

## 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.

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

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

### 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 : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

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. 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. Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

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

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

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
Starch	9005-25-8	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
		STEL (inhalable dust)	20 mg/m3	GB EH40
Ramipril	87333-19-5	TWA	3 μg/m3 (OEB 4)	Internal
		Wipe limit	30 μg/100cm2	Internal

### 8.2 Exposure controls

### **Engineering measures**

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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 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: No data availableOdour: No data availableOdour 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 : Not applicable

Evaporation rate : Not applicable

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

dling or other means.

Upper explosion limit / Upper : No data available

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



# **Ramipril Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 9374091-00008 Date of first issue: 27.08.2021

flammability limit

Lower explosion limit / Lower : No data available

flammability limit

Vapour pressure Not applicable

Relative vapour density Not applicable

Relative density No data available

Density No data available

Solubility(ies)

Water solubility No data available Partition coefficient: n-Not applicable

octanol/water

No data available Auto-ignition temperature

Decomposition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Not explosive Explosive properties

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

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, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid Heat, flames and sparks.

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

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**

Not classified based on available information.

#### Components:

Ramipril:

Acute oral toxicity : LD50 (Rat): > 10,000 mg/kg

LD50 (Dog): > 1,000 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Dog): > 250 mg/kg

Application Route: Intravenous

LD50 (Rat): 600 mg/kg

Application Route: Intravenous

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

# Skin corrosion/irritation

Not classified based on available information.

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



# **Ramipril Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 9374091-00008 Date of first issue: 27.08.2021

### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

Starch:

Species : Rabbit

Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

### Respiratory sensitisation

Not classified based on available information.

### **Components:**

#### **Natural Pork Flavor:**

Assessment : The product is a skin sensitiser, sub-category 1B.

## Starch:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

#### Germ cell mutagenicity

Not classified based on available information.

# **Components:**

## Ramipril:

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

Result: negative

Test Type: unscheduled DNA synthesis assay

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: mice Result: negative

Starch:

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

Result: negative

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

# Carcinogenicity

Not classified based on available information.

#### **Components:**

Ramipril:

Species : Rat Application Route : Oral

Exposure time : 24 month(s)

NOAEL : 500 mg/kg body weight

Result : negative

Species : Rat Application Route : Oral

Exposure time : 18 month(s)

NOAEL : 1,000 mg/kg body weight

Result : negative

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

#### Reproductive toxicity

May damage the unborn child.

### **Components:**

Ramipril:

Effects on fertility : Test Type: Fertility

Species: Rat

**Application Route: Oral** 

Fertility: NOAEL: 500 mg/kg body weight

Result: No adverse effects

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

**Application Route: Oral** 

Developmental Toxicity: NOAEL: 10 mg/kg body weight

Result: Malformations were observed.

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 50 mg/kg body weight

Result: Malformations were observed.

Test Type: Development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 0.4 mg/kg body weight

Result: Maternal toxicity observed.

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 1 mg/kg body weight

Result: Maternal toxicity observed.

Test Type: Development Species: Monkey

Application Route: Oral

Developmental Toxicity: NOAEL: 5 mg/kg body weight

Result: Maternal toxicity observed.

Test Type: Development

Species: Monkey Application Route: Oral

Developmental Toxicity: LOAEL: 50 mg/kg body weight

Result: Maternal toxicity observed.

Reproductive toxicity - As-

sessment

May damage the unborn child.

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

**Application Route: Ingestion** 

Result: negative

### STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

#### **Components:**

Ramipril:

Exposure routes : Oral Target Organs : Kidney

Assessment : May cause damage to organs through prolonged or repeated

exposure.

## Repeated dose toxicity

# **Components:**

Ramipril:

Species : Mouse LOAEL : 100 mg/kg Application Route : Oral

Target Organs : Blood, Kidney Symptoms : kidney effects

Species : Rat
NOAEL : 2 mg/kg
Application Route : Oral

Species : Dog
NOAEL : 2.5 mg/kg
LOAEL : 250 mg/kg
Application Route : Oral

Target Organs : Blood, Kidney Symptoms : kidney effects

Species : Monkey
NOAEL : 8 mg/kg
LOAEL : 250 mg/kg
Application Route : Oral

Target Organs : Blood, Kidney Symptoms : kidney effects

Starch:

Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

Cellulose:

Species : Rat

NOAEL : >= 9,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

#### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

## **Components:**

## Ramipril:

Ingestion : Symptoms: Allergic reactions, Kidney disorders, liver function

change, Rash, Cough, Dizziness, Nausea, Headache, Vomit-

ing

# **SECTION 12: Ecological information**

#### 12.1 Toxicity

## **Components:**

Ramipril:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

# **Hydrolyzed Vegetable Protein:**

# **Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

### **Natural Pork Flavor:**

### **Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

#### **Hydrogenated Vegetable Oil:**

# **Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

### 12.2 Persistence and degradability

# **Components:**

Ramipril:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 20 - 50 %

Exposure time: 28 d

Method: OECD Test Guideline 301A

Cellulose:

Biodegradability : Result: Readily biodegradable.

## 12.3 Bioaccumulative potential

No data available

# 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 poten-

tial

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

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.

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



# **Ramipril Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 9374091-00008 Date of first issue: 27.08.2021

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 : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

# 14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

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



# Ramipril Formulation

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

## **SECTION 15: Regulatory information**

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

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 : Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone : Not applicable

layer

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Not applicable

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

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.

**Full text of H-Statements** 

H317 : May cause an allergic skin reaction. H360D : May damage the unborn child.

H373 : May cause damage to organs through prolonged or repeated

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



# **Ramipril Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 28.09.2024 9374091-00008 Date of first issue: 27.08.2021 4.3

exposure if swallowed.

#### Full text of other abbreviations

Repr. Reproductive toxicity Skin Sens. Skin sensitisation

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) Short-term exposure limit (15-minute reference period) GB EH40 / STEL

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; 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**

compile the Safety Data Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

### Classification of the mixture:

#### Classification procedure:

Skin Sens. 1 Calculation method H317 H360D Repr. 1A Calculation method

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



# **Ramipril Formulation**

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

 4.3
 28.09.2024
 9374091-00008
 Date of first issue: 27.08.2021

STOT RE 2 H373 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