SAFETY DATA SHEET

Ramipril Formulation

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 Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   20 Spartan Road
   1619 Spartan, South Africa
   Telephone : +27119239300
   E-mail address of person responsible for the SDS : EHSDATALTEWARD@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)
   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   H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   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

Additional Labelling
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>EC-No.</td>
<td>Index-No.</td>
<td>Registration number</td>
</tr>
<tr>
<td>Ramipril</td>
<td>87333-19-5</td>
<td>Repr. 1A; H360D</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT RE 2; H373</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Kidney)</td>
<td></td>
</tr>
<tr>
<td>Hydrolyzed Vegetable Protein</td>
<td>Not Assigned</td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Natural Pork Flavor</td>
<td>Not Assigned</td>
<td>Skin Sens. 1B; H317</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Hydrogenated Vegetable Oil</td>
<td>Not Assigned</td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

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 an 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.

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: 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

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media


Unsuitable extinguishing: None known.
5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:
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

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 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 assessment. 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.

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 Organic peroxides Explosives Gases

7.3 Specific end use(s)

Specific use(s): No data available
## 8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
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<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA OEL-RL (Respirable dust)</td>
<td>5 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Further information:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Recommended Limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA OEL-RL (inhalable dust)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
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<td>Further information:</td>
<td></td>
<td></td>
</tr>
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<td></td>
<td>Recommended Limit</td>
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<td></td>
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<td>Recommended Limit</td>
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<td>Ramipril</td>
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<td></td>
<td>Wipe limit</td>
<td>30 µg/100cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

## 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 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 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 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: No data available

Odour: No data available

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: Not applicable

Evaporation rate: Not applicable

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: 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-octanol/water: Not applicable

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity

Viscosity, kinematic: Not applicable

Explosive properties: Not explosive
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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
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): LD50 (Dog): > 250 mg/kg
**SAFETY DATA SHEET**

**Ramipril Formulation**

**Version** 1.4  
**Revision Date:** 09.04.2021  
**SDS Number:** 3517209-00005  
**Date of last issue:** 10.10.2020  
**Date of first issue:** 11.10.2018

**Administration**  
Application Route: Intravenous  
LD50 (Rat): 600 mg/kg  
Application Route: Intravenous

**Skin corrosion/irritation**  
Not classified based on available information.

**Serious eye damage/eye irritation**  
Not classified based on available information.

**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.

**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

**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

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 development
Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 10 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 - Assessment: May damage the unborn child.

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
May cause damage to organs through prolonged or repeated exposure.

**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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>2 mg/kg</td>
<td>Oral</td>
<td>Blood, Kidney</td>
<td>kidney effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
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<td>Oral</td>
<td>Blood, Kidney</td>
<td>kidney effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkey</td>
<td>8 mg/kg</td>
<td>Oral</td>
<td>Blood, Kidney</td>
<td>kidney effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkey</td>
<td>250 mg/kg</td>
<td>Oral</td>
<td>Blood, Kidney</td>
<td>kidney effects</td>
</tr>
</tbody>
</table>

**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-
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Ramipril:**
- Toxicity to fish: $LC_{50} (Brachydanio rerio (zebrafish))$: > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates: $EC_{50} (Daphnia magna (Water flea))$: > 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants: $EC_{50} (Pseudokirchneriella subcapitata (green algae))$: > 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

12.2 Persistence and degradability

**Components:**

**Ramipril:**
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 20 - 50%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301A
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Version 1.4  Revision Date: 09.04.2021  SDS Number: 3517209-00005  Date of last issue: 10.10.2020
Date of first issue: 11.10.2018

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 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.

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.

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
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
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.

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:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
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</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

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 exposure if swallowed.

Full text of other abbreviations

Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

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

Version 1.4
Revision Date: 09.04.2021
SDS Number: 3517209-00005
Date of last issue: 10.10.2020
Date of first issue: 11.10.2018

Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
Skin Sens. 1 H317 Calculation method
Repr. 1A H360D Calculation method
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.

ZA / EN