SAFETY DATA SHEET
Ramipril Formulation

SECTION 1. IDENTIFICATION

Product name: Ramipril Formulation

Manufacturer or supplier's details
Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Skin sensitization: Category 1
Reproductive toxicity: Category 1A
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Kidney)

GHS label elements
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 (Kidney) through prolonged or repeated exposure if swallowed.

Precautionary Statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protec-
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Version 2.3  Revision Date: 27.08.2021  SDS Number: 3517179-00006  Date of last issue: 10.10.2020  Date of first issue: 11.10.2018

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**Response:**

- **P302 + P352** IF ON SKIN: Wash with plenty of water.
- **P308 + P313** IF exposed or concerned: Get medical advice/attention.
- **P333 + P313** If skin irritation or rash occurs: Get medical advice/attention.
- **P362 + P364** Take off contaminated clothing and wash it before reuse.

**Storage:**

- P405 Store locked up.

**Disposal:**

- P501 Dispose of contents/container to an approved waste disposal plant.

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**Additional Labeling**

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

**Other hazards which do not result in classification**

- 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.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

| Substance / Mixture | Components
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>Starch 9005-25-8 &gt;= 30 &lt; 50</td>
</tr>
<tr>
<td>Cellulose</td>
<td>Cellulose 9004-34-6 &gt;= 30 &lt; 50</td>
</tr>
<tr>
<td>Ramipril</td>
<td>Ramipril 87333-19-5 &gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Hydrolyzed Vegetable Protein</td>
<td>Not Assigned &gt;= 5 &lt; 10</td>
</tr>
<tr>
<td>Natural Pork Flavor</td>
<td>Natural Pork Flavor Not Assigned &gt;= 1 &lt; 5</td>
</tr>
<tr>
<td>Hydrogenated Vegetable Oil</td>
<td>Hydrogenated Vegetable Oil Not Assigned &gt;= 1 &lt; 5</td>
</tr>
</tbody>
</table>

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**SECTION 4. FIRST AID MEASURES**

**General advice**

In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

**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.
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.

Most important symptoms and effects, both acute and delayed:
- May cause an allergic skin reaction.
- May damage the unborn child.
- May cause damage to organs through prolonged or repeated exposure if swallowed.
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.

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).

Notes to physician:
Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
None known.

Specific hazards during fire fighting:
- Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides

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.

Special protective equipment for fire-fighters:
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.
Methods and materials for containment and 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.

SECTION 7. HANDLING AND STORAGE

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.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
</table>

4 / 15
Starch | 9005-25-8 | CMP | 10 mg/m³ | AR OEL | Further information: A4 - Not classifiable as a human carcinogen
---|---|---|---|---|---
|  |  | TWA | 10 mg/m³ | ACGIH |
Cellulose | 9004-34-6 | CMP | 10 mg/m³ | AR OEL | TWA | 10 mg/m³ | ACGIH |
Ramipril | 87333-19-5 | TWA | 3 µg/m³ (OEB 4) | Internal | Wipe limit | 30 µg/100cm² | Internal |

**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**

**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

**Hand protection**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**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.

**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.

**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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
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<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
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<tr>
<td>Relative vapor density</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
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<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic: Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks. Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

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

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
Skin corrosion/irritation
Not classified based on available information.

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

Components:
Starch:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization
Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.

Components:
Starch:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Natural Pork Flavor:
Assessment: The product is a skin sensitizer, sub-category 1B.

Germ cell mutagenicity
Not classified based on available information.

Components:
Starch:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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
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:

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

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:

Cellulose:
Effects on fertility:
Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development:
Test Type: Fertility/early embryonic development
Species: Rat
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Application Route: Ingestion
Result: negative

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 fetal 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: 50 mg/kg body weight
Result: Malformations were 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 (Kidney) through prolonged or repeated exposure if swallowed.
Components:

Ramipril:
- Routes of exposure: Oral
- Target Organs: Kidney
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

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

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

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, Vomiting

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:
Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

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

Persistence and degradability

Components:

Cellulose:
Biodegradability : Result: Readily biodegradable.

Ramipril:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 20 - 50 %
Exposure time: 28 d
Method: OECD Test Guideline 301A

Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
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

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Special precautions for user
Not applicable
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SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry: Not applicable

Control of precursors and essential chemicals for the preparation of drugs: Not applicable

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

AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information


Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

AR OEL: Argentina. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average

AR OEL / CMP: TLV (Threshold Limit Value)

All abbreviations explained:
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.