SAFETY DATA SHEET

Ramipril Formulation

SECTION 1. IDENTIFICATION

Product name: Ramipril Formulation

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
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: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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 must not be allowed out of
the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 IF skin irritation or rash occurs: Get medical attention.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Ramipril</td>
<td>87333-19-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Hydrolyzed Vegetable Protein</td>
<td>Not Assigned</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Natural Pork Flavor</td>
<td>Not Assigned</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Hydrogenated Vegetable Oil</td>
<td>Not Assigned</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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.
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.

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

**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 spills 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
- Self-reactive substances and mixtures
- Organic peroxides
- Explosives
- Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td></td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>15 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td></td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
</tbody>
</table>
5 mg/m³
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

15 Million particles per cubic foot
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

5 mg/m³
Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
--- | --- | --- | --- | --- |
Starch | 9005-25-8 | TWA | 10 mg/m³ | ACGIH |
| | | TWA (Respirable) | 5 mg/m³ | NIOSH REL |
| | | TWA (total) | 10 mg/m³ | NIOSH REL |
| | | TWA (total dust) | 15 mg/m³ | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m³ | OSHA Z-1 |
Cellulose | 9004-34-6 | TWA | 10 mg/m³ | ACGIH |
| | | TWA (Respirable) | 5 mg/m³ | NIOSH REL |
| | | TWA (total) | 10 mg/m³ | NIOSH REL |
| | | TWA (total dust) | 15 mg/m³ | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m³ | OSHA Z-1 |
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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are
unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material: 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

Appearance: powder

Color: No data available

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reactivity</strong></td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td><strong>Chemical stability</strong></td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td><strong>Possibility of hazardous reactions</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td><strong>Conditions to avoid</strong></td>
<td>Heat, flames and sparks.</td>
</tr>
</tbody>
</table>

### Flash point
- **Not applicable**

### Evaporation rate
- **Not applicable**

### Flammability (solid, gas)
- May form explosive dust-air mixture during processing, handling 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**

### Vapor pressure
- **Not applicable**

### Relative vapor 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**

### Autoignition temperature
- **No data available**

### Decomposition temperature
- **No data available**

### Viscosity
- **Viscosity, kinematic**: **Not applicable**

### Explosive properties
- **Not explosive**

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

### Molecular weight
- **No data available**

### Particle size
- **No data available**
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
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
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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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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
  - Application Route: Ingestion
  - Result: negative
### Ramipril:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Fertility: NOAEL: 500 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: No adverse effects.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
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<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 10 mg/kg body weight</td>
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<tr>
<td>Result: Malformations were observed.</td>
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</table>

<table>
<thead>
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<th>Test Type: Development</th>
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</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 50 mg/kg body weight</td>
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<tr>
<td>Result: Malformations were observed.</td>
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</tbody>
</table>

<table>
<thead>
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<th>Test Type: Development</th>
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</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 0.4 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Maternal toxicity observed.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 1 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Maternal toxicity observed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Monkey</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 5 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Maternal toxicity observed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Monkey</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 50 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Maternal toxicity observed.</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Ramipril:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure: Oral</td>
</tr>
</tbody>
</table>
Target Organs: Kidney
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Starch:
Species: Rat
NOAEL: \( \geq 2,000 \text{ mg/kg} \)
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

Cellulose:
Species: Rat
NOAEL: \( \geq 9,000 \text{ mg/kg} \)
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. Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

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.

Domestic regulation

49 CFR
Not regulated as a dangerous good
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Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Respiratory or skin sensitization
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Cellulose 9004-34-6
- Starch 9005-25-8
- Ramipril 87333-19-5
- Hydrolyzed Vegetable Protein Not Assigned
- Natural Pork Flavor Not Assigned

California Prop. 65
WARNING: This product can expose you to chemicals including Ramipril, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants
- Cellulose 9004-34-6
- Starch 9005-25-8

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
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Version 3.0
Revision Date: 04/04/2023
SDS Number: 3517208-00009
Date of last issue: 10/01/2022
Date of first issue: 10/11/2018

NFPA 704:  

<table>
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<tr>
<th>Flammability</th>
<th>Instability</th>
<th>Special hazard</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

- **HEALTH**: 2
- **FLAMMABILITY**: 3
- **PHYSICAL HAZARD**: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **CAL PEL**: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
- **NIOSH REL**: USA. NIOSH Recommended Exposure Limits
- **OSHA Z-1**: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- **OSHA Z-3**: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CAL PEL / PEL**: Permissible exposure limit
- **NIOSH REL / TWA**: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- **OSHA Z-1 / TWA**: 8-hour time weighted average
- **OSHA Z-3 / TWA**: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; KECl - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-
SAFETY DATA SHEET

Ramipril Formulation

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Revision Date: 04/04/2023

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

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US / Z8