SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ramipril Formulation

Version 1.2 Revision Date: 09/13/2019 SDS Number: 3517174-00003 Date of last issue: 2019/04/24 Date of first issue: 2018/10/11

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ramipril Formulation

Manufacturer or supplier’s details
Company: MSD
Address: No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: powder
Colour: No data available
Odour: No data available

May cause an allergic skin reaction. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

GHS Classification
Skin sensitisation: Category 1
Reproductive toxicity: Category 1A
Specific target organ toxicity - repeated exposure: Category 2

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 through prolonged or repeated exposure.
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 protection/ face protection.

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.

Physical and chemical hazards
Not classified based on available information.

Health hazards
May cause an allergic skin reaction. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards
Not classified based on available information.

Additional Labelling
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.

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

### 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**: 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.

**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.

### 5. FIREFIGHTING MEASURES

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

**Unsuitable extinguishing media**: None known.

**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

**Specific extinguishing method**: Use extinguishing measures that are appropriate to local cir-
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions

- Discharge into the environment must be avoided.
- 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.

7. HANDLING AND STORAGE

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.

Avoidance of contact: Oxidizing agents

Storage

Conditions for safe storage: Keep in properly labelled 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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m3</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td>Ramipril</td>
<td>87333-19-5</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>3 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>30 µg/100cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

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.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the
Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash 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.

9. 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.

Flammability (liquids) : No data available

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
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: No data available

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.

11. TOXICOLOGICAL INFORMATION
Exposure routes: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity: Not classified based on available information.

Components:
Starch:
Acute oral toxicity:  LD50 (Mouse): > 5,000 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.

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 sensitizer, sub-category 1B.

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
Genotoxicity in vitro:  Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: In vitro mammalian cell gene mutation test
  Result: negative
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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
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Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development:
- Test Type: Fertility/early embryonic development
  - Species: Rat
  - 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 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 - As:
- 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:

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

### 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 (Brachydaniio 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
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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

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.

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.

National Regulations

GB 6944/12268
Not regulated as a dangerous good
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Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average
GBZ 2.1-2007 / PC-TWA : Permissible concentration - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect
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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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.

CN / EN