SAFETY DATA SHEET

Lisinopril Formulation

Version 3.2 Revision Date: 09/13/2019 SDS Number: 50010-00014 Date of last issue: 04/24/2019
Date of first issue: 01/26/2015

SECTION 1. IDENTIFICATION

Product name: Lisinopril Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity: Category 1A
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Kidney)

GHS label elements
Hazard pictograms:

Signal Word: Danger

Hazard Statements: 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/ fume/ gas/ mist/ vapors/ spray.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/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.
- May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>Chemical name: Starch, CAS-No.: 9005-25-8, Concentration (% w/w): &gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>Chemical name: Lisinopril, CAS-No.: 83915-83-7, Concentration (% w/w): &gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range 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.

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 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
Metal oxides
Oxides of phosphorus

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 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 cleanup
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.
Local/Total ventilation: If sufficient ventilation is unavailable, use 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>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>83915-83-7</td>
<td>TWA</td>
<td>40 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
- Minimize workplace exposure concentrations.
- Apply measures to prevent dust explosions.
- Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
- If sufficient ventilation is unavailable, use local exhaust ventilation.
ventilation. Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

**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  
Material: Chemical-resistant gloves  
Remarks: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

**Eye protection**: Wear the following personal protective equipment: Safety goggles  

**Skin and body protection**: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).  

**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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: powder  
**Color**: No data available  
**Odor**: odorless  
**Odor Threshold**: No data available  
**pH**: No data available  
**Melting point/freezing point**: No data available
### Initial boiling point and boiling range
- **Initial boiling point and boiling range**: No data available

### Flash point
- **Flash point**: No data available

### Evaporation rate
- **Evaporation rate**: No data available

### Flammability (solid, gas)
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.

### Flammability (liquids)
- **Flammability (liquids)**: No data available

### Upper explosion limit / Upper flammability limit
- **Upper explosion limit / Upper flammability limit**: No data available

### Lower explosion limit / Lower flammability limit
- **Lower explosion limit / Lower flammability limit**: No data available

### Vapor pressure
- **Vapor pressure**: No data available

### Relative vapor density
- **Relative vapor density**: No data available

### Density
- **Density**: No data available

### Solubility(ies)
- **Solubility(ies)**:
  - **Water solubility**: No data available

### Partition coefficient: n-octanol/water
- **Partition coefficient: n-octanol/water**: No data available

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

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

### Viscosity
- **Viscosity**:
  - **Viscosity, dynamic**: No data available
  - **Viscosity, kinematic**: No data available

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

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

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

### Particle size
- **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.
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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 (Mouse): > 5,000 mg/kg

Lisinopril:
Acute oral toxicity: LD50 (Rat): > 20,000 mg/kg
LD50 (Mouse): > 20,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
Lisinopril:
Species: Rabbit
Result: Mild skin irritation

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

Components:
Lisinopril:
Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.
Components:

Lisinopril:

Test Type: Maximization Test
Routes of exposure: Dermal
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Lisinopril:

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

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster lung cells
Result: negative

Test Type: Alkaline elution assay
Test system: rat hepatocytes
Result: negative

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Lisinopril:

Species: Rat
Application Route: Oral
Exposure time: 105 weeks
NOAEL: 90 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 92 weeks
NOAEL: 135 mg/kg body weight
Result: negative

Reproductive toxicity
May damage the unborn child.

Components:

Lisinopril:

Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 300 mg/kg body weight
Symptoms: No effects on mating performance.
Result: Animal testing did not show any effects on fertility.

Effects on fetal development:
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight
Symptoms: Total Resorptions / resorption rate.
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Symptoms: Total Resorptions / resorption rate.
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 0.1 mg/kg body weight
Symptoms: Embryotoxic effects and adverse effects on the offspring were detected.

Reproductive toxicity - Assessment:
Positive evidence of adverse effects on development from human epidemiological studies.

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:

Lisinopril:
Routes of exposure: Ingestion
Target Organs: Kidney
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Lisinopril:
Species: Rat
LOAEL: < 3,650 mg/kg
Application Route: Oral
Exposure time: 1 y
Target Organs: Kidney
SECTION 1. IDENTIFICATION

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**Lisinopril Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.2</td>
<td>09/13/2019</td>
<td>50010-00014</td>
<td>04/24/2019</td>
<td>01/26/2015</td>
</tr>
</tbody>
</table>

Species: Dog
LOAEL: < 840 mg/kg
Application Route: Oral
Exposure time: 4 Weeks
Target Organs: Kidney

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Lisinopril:**
Ingestion: Symptoms: Dizziness, Headache, Fatigue, Diarrhea, Nausea, Cough, Lowered blood pressure, electrolyte imbalance
Remarks: May damage the unborn child.

SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Lisinopril:**
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 20,000 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

**Persistence and degradability**
No data available

**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
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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**

**TDG**
Not regulated as a dangerous good

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**SECTION 15. REGULATORY INFORMATION**

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

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

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**SECTION 16. OTHER INFORMATION**

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>CA AB OEL</td>
<td>Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)</td>
</tr>
<tr>
<td>CA BC OEL</td>
<td>Canada. British Columbia OEL</td>
</tr>
<tr>
<td>CA QC OEL</td>
<td>Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>CA AB OEL / TWA</td>
<td>8-hour Occupational exposure limit</td>
</tr>
<tr>
<td>CA BC OEL / TWA</td>
<td>8-hour time weighted average</td>
</tr>
<tr>
<td>CA QC OEL / TWAEV</td>
<td>Time-weighted average exposure value</td>
</tr>
</tbody>
</table>

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; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Con-
Sources of key data used to compile the Material Safety Data Sheet

Revision Date : 09/13/2019

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.

CA / Z8