1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Lisinopril Formulation

Supplier’s company name, address and phone number

Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Number: Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity: Category 1A

GHS label elements
Hazard pictograms: 
Signal word: Danger
Hazard statements: H360D May damage the unborn child.
Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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.
SAFETY DATA SHEET

Lisinopril Formulation

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed
- 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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 20</td>
<td>8-98</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>83915-83-7</td>
<td>1 - &lt; 10</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 damage the unborn child.
- 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
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 firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

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

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.

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

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Lisinopril</td>
<td>83915-83-7</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 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 with local exhaust ventilation.

Personal protective equipment

Respiratory protection
: If adequate local exhaust ventilation is not available or expo-
Filter type: Particulates type  
Hand protection: 
Material: Chemical-resistant gloves  
Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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).

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: powder  
Colour: No data available  
Odour: odourless  
Odour Threshold: No data available  
Melting point/freezing point: No data available  
Boiling point, initial boiling point and boiling range: No data available  
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): No data available  
Lower explosion limit and upper explosion limit / flammability limit: No data available  
Upper explosion limit / Upper flammability limit: No data available  
Lower explosion limit / Lower flammability limit: No data available  
Flash point: No data available  
Decomposition temperature: No data available  
pH: No data available
Evaporation rate : No data available
Auto-ignition temperature : No data available

Viscosity
  Viscosity, dynamic : No data available
  Viscosity, kinematic : No data available

Solubility(ies)
  Water solubility : No data available

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

Vapour pressure : No data available

Density and / or relative density
  Density : No data available
  Relative vapour density : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
  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 reac-
tions : May form explosive dust-air mixture during processing, han-
dling 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

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

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:
Starch:
Species: Rabbit
Result: No eye irritation

Lisinopril:
Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Starch:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
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Version 3.1  Revision Date: 2020/10/01  SDS Number: 50019-00015  Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

Lisinopril:
Test Type: Maximisation Test
Exposure routes: Dermal
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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 foetal development:
- Test Type: 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
- Result: 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
Not classified based on available information.

Components:

Lisinopril:
- Exposure routes: Ingestion
- 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

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

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, Diarrhoea, Nausea, Cough, Lowered blood pressure, electrolyte imbalance
Remarks: May damage the unborn child.

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

Hazardous to the ozone layer
Not applicable
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
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable
Waste Disposal and Public Cleansing Law

Industrial waste

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

Sources of key data used to compile the Safety Data Sheet:
- Date format: yyyy/mm/dd

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

All information provided by AICM: Australia Inventory of Industrial Chemicals; 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 Standardisation; 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 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
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.

JP / EN