

Lisinopril Formulation

Version 3.9 Revision Date: 04/09/2022 SDS Number: 50010-00021 Date of last issue: 03/26/2022
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 : 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 : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

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

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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.
Storage:
P405 Store locked up.

Lisinopril Formulation

Version 3.9 Revision Date: 04/09/2022 SDS Number: 50010-00021 Date of last issue: 03/26/2022
 Date of first issue: 01/26/2015

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.
 May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Starch	Sago starch	9005-25-8	>= 10 - < 30 *
Lisinopril	No data available	83915-83-7	>= 5 - < 10 *

* 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.
- 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.
 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

Lisinopril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.9	04/09/2022	50010-00021	Date of first issue: 01/26/2015

- 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 (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.

Lisinopril Formulation

Version 3.9 Revision Date: 04/09/2022 SDS Number: 50010-00021 Date of last issue: 03/26/2022
 Date of first issue: 01/26/2015

- Local/Total ventilation : Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
 : 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m ³	CA AB OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m ³	CA BC OEL
		TWAEV (total dust)	10 mg/m ³	CA QC OEL
		TWA	10 mg/m ³	ACGIH
Lisinopril	83915-83-7	TWA	4 µg/m ³ (OEB 4)	Internal
		Wipe limit	40 µg/100 cm ²	Internal

- 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

Lisinopril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.9	04/09/2022	50010-00021	Date of first issue: 01/26/2015

work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust 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 |
| Hand protection | : | |
| 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. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|----------------|---|-------------------|
| Appearance | : | powder |
| Color | : | No data available |
| Odor | : | odorless |
| Odor Threshold | : | No data available |
| pH | : | No data available |

Lisinopril Formulation

Version Revision Date: SDS Number: Date of last issue: 03/26/2022
3.9 04/09/2022 50010-00021 Date of first issue: 01/26/2015

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

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 : No data available

Relative vapor density : No data available

Density : No data available

Solubility(ies)
 Water solubility : No data available

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
 Viscosity, dynamic : No data available

 Viscosity, kinematic : No data available

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : May form explosive dust-air mixture during processing,

Lisinopril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.9	04/09/2022	50010-00021	Date of first issue: 01/26/2015

tions	handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Starch:

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg

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

Lisinopril Formulation

Version 3.9 Revision Date: 04/09/2022 SDS Number: 50010-00021 Date of last issue: 03/26/2022
Date of first issue: 01/26/2015

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Starch:

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

Lisinopril:

Test Type : Maximization Test
Routes of exposure : 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

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Lisinopril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.9	04/09/2022	50010-00021	Date of first issue: 01/26/2015

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 : Test Type: Development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 30 mg/kg body weight
 Result: positive, No teratogenic effects.

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.

Lisinopril Formulation

Version 3.9 Revision Date: 04/09/2022 SDS Number: 50010-00021 Date of last issue: 03/26/2022
Date of first issue: 01/26/2015

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:

Starch:

Species : Rat
NOAEL : $\geq 2,000$ mg/kg
Application Route : Skin contact
Exposure time : 28 Days
Method : OECD Test Guideline 410

Lisinopril:

Species : Rat
LOAEL : 2 mg/kg
Application Route : Oral
Exposure time : 1 y
Target Organs : Kidney

Species : Dog
LOAEL : 15 mg/kg
Application Route : Oral
Exposure time : 1 y
Target Organs : Kidney

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Lisinopril:

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

Lisinopril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.9	04/09/2022	50010-00021	Date of first issue: 01/26/2015

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

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

Special precautions for user

Not applicable

Lisinopril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.9	04/09/2022	50010-00021	Date of first issue: 01/26/2015

SECTION 15. REGULATORY INFORMATION

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

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

AIIIC - Australian 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 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 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

Lisinopril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.9	04/09/2022	50010-00021	Date of first issue: 01/26/2015

stances 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 04/09/2022
Date format : mm/dd/yyyy

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.

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