

SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product name: LOSARTAN POTASSIUM TABLETS**SDS No:** P00000020029**Synonyms, Trade Names:**

LORZAAR 12.5 mg START, LORTAAN CARDIOSTART, LOSAPREX CARDIOSTAT, NEOLOTAN CARDIOSTART, COZAAR PLUS FORTE, LORZAAR PROTECT, COZAAR INICIO, COZAAR START, NEOLOTAN, COZAAREX, LOSAPREX, NU-LOTAN, LORTAAN, COSAAR, OCSAAR

IUPAC:

[2-butyl-5-chloro-3-[[4-[2-(2H-tetrazol-5-yl)phenyl]phenyl]methyl]imidazol-4-yl]methanol

Manufacturer:

Merck
One Merck Drive P.O. Box 100
Whitehouse Station, NJ, USA 08889-0100

Telephone: 908-423-1000 (General Information Only)**Fax:** 908-735-1496**Contact Person:** EHS Data Steward**e-mail:** MSDS@merck.com**Emergency telephone:** 1-908-423-6000 (24/7/365) English Only**Intended Use:** Finished pharmaceutical product.

2 HAZARDS IDENTIFICATION

Emergency Overview:**Appearance:**

Form : Tablets
Odor: Odorless

Signal words WARNING!

Potential Health Effects:

General Avoid contact with eyes and prolonged or repeated contact with skin. Wash thoroughly after handling. No specific hazard with intact tablets or capsules.

Potential Physical / Chemical Effects:

None under normal conditions.

skin: Slightly irritating. May cause sensitization by skin contact.

eye: Severely irritating to eyes. Risk of serious damage to eyes.

Ingestion: Harmful if swallowed.

Signs and Symptoms: Hypotension (low blood pressure).

Routes of Exposure:	Inhalation
Target Organs:	Cardiovascular System, kidney, Stomach
OSHA Regulatory Status	This product is hazardous according to OSHA 29CFR 1910.1200.
OTHER INFORMATION	No additional information

3 COMPOSITION / INFORMATION ON INGREDIENTS

General information: The formulations for these products are proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

Hazardous Component(s):

Chemical name	CAS-No.	Concentration
Cellulose Microcrystalline	9004-34-6	30 - 60%
Losartan Potassium	124750-99-8	24%
Starch	9005-25-8	10 - 30%
Titanium Dioxide	13463-67-7	<1%
SILICON DIOXIDE	7631-86-9	<0.1%
ALUMINUM HYDROXIDE, HYDRATED	21645-51-2	<0.1%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4 FIRST AID MEASURES

Inhalation:	Move to fresh air. For breathing difficulties, oxygen may be necessary. If breathing stops, provide artificial respiration. Get medical attention.
Skin contact:	Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing.
Eye contact:	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if symptoms occur.
Ingestion:	Do not induce vomiting. Get medical attention if symptoms occur.
Notes to the physician:	
Hazards:	See Sections 2 and 11.
Treatment:	Treat supportively and symptomatically.

5 FIRE-FIGHTING MEASURES

Extinguishing media:	Water spray, fog, CO ₂ , dry chemical, or alcohol resistant foam.
Unsuitable extinguishing media:	None known.
Unusual Fire & Explosion Hazards:	Emits toxic fumes under fire conditions.
Special Fire Fighting Procedures:	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Keep unnecessary personnel away.

Environmental precautions: Do not release into the environment.

Spill Cleanup Methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Avoid dusty conditions and prevent wind dispersal. Collect in containers and seal securely. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

7 HANDLING AND STORAGE

Handling: No specific hazard with intact tablets or capsules. In case of exposure to crushed or broken tablets/capsules, avoid contact with eyes and avoid prolonged or repeated contact with skin. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

Chemical name	Type	Exposure Limit values	Source
Cellulose Microcrystalline	TWA	10 mg/m3	US. ACGIH Threshold Limit Values (2009)
Cellulose Microcrystalline - Total dust.	PEL	15 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Cellulose Microcrystalline - Respirable fraction.	PEL	5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Starch	TWA	10 mg/m3	US. ACGIH Threshold Limit Values (2009)
Starch - Respirable fraction.	PEL	5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Starch - Total dust.	PEL	15 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Titanium Dioxide	TWA	10 mg/m3	US. ACGIH Threshold Limit Values (2009)
Titanium Dioxide - Total dust.	PEL	15 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
ALUMINUM HYDROXIDE, HYDRATED - Respirable fraction.	TWA	1 mg/m3	US. ACGIH Threshold Limit Values (2009)
Losartan Potassium	TWA	100 ug/m3 (OEB 2)	Merck
	Wipe Limit	1,000 ug/100 cm2	Merck

OEB (Occupational Exposure Band) is an internal Merck control band.

Protective Measures: No special containment required with normal handling of finished product. Use

local exhaust ventilation to control residual dust from broken or crushed tablets when handling in bulk quantities.

Respiratory Protection:	No specific recommendation made, but respiratory protection must be used if the general level exceeds the Recommended Occupational Exposure Limit
Hand protection:	Disposable chemical resistant gloves wherever the potential exists for direct exposure to residual dust from crushed or broken tablets or capsules.
Eye protection:	If contact is likely, safety glasses with side shields are recommended.
Skin and Body Protection:	Work uniform or laboratory coat when there is potential for direct contact with the residual dust from crushed or broken tablets.
Hygiene measures:	Wash skin thoroughly with soap and water.

9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance:

Physical State:	Solid
Form:	Tablets
Odor:	Odorless
Flammability (solid, gas):	Noncombustible Solid

10 STABILITY AND REACTIVITY

Stability:	Stable
Possibility of hazardous reactions:	Stable
Conditions to avoid:	Moisture. Excessive heat.
Incompatible materials:	None under normal conditions.
Hazardous decomposition products:	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

11 TOXICOLOGICAL INFORMATION

General information:	The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.
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Specified substance(s):

Acute Toxicity (Oral); Name	Test results
Cellulose Microcrystalline	LD50 (Rat): > 5,000 mg/kg
Losartan Potassium	LD50 (Mouse): 1,257 - 1,590 mg/kg LDLo (Mouse): 400 mg/kg LDLo (Rat): 200 mg/kg
Starch	No data available.
Titanium Dioxide	No data available.
SILICON DIOXIDE	LD50 (Mouse): > 15,000 mg/kg LD50 (Rat): > 22,500 mg/kg
ALUMINUM HYDROXIDE, HYDRATED	LD50 (Rat): > 5,000 mg/kg
Acute Toxicity (Dermal); Name	Test results
Cellulose Microcrystalline	LD50 (Rabbit): > 2,000 mg/kg
Losartan Potassium	No data available.
Starch	No data available.
Titanium Dioxide	No data available.
Acute Toxicity (Inhalation); Name	Test results
Cellulose Microcrystalline	LC50 (Rat, 4 h): > 5.05 mg/l
Losartan Potassium	No data available.
Starch	No data available.
Titanium Dioxide	No data available.
Repeated dose toxicity: Name	Test results
Cellulose Microcrystalline	No data available.
Losartan Potassium	LOAEL (Rat, Oral, 370 d, daily): 15 mg/kg (Target Organ(s): blood, kidney, stomach, cardiovascular system)
Starch	No data available.
Titanium Dioxide	No data available.
Inhalation:	No data available.
Ingestion:	No data available.
Skin corrosion/irritation:	No data available.
Serious eye damage/eye irritation:	No data available.
Respiratory sensitizer/Skin sensitizer:	No data available.
Carcinogenicity:	No data available.

The following components have been identified as having carcinogenic properties

Name	CAS-No.	Concentration
Titanium Dioxide	13463-67-7	<1%

Mutagenesis: No data available.

Reproductive toxicity: No data available.

12 ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: No additional information

Specified substance(s):

Acute toxicity(Fish):

Name	Test results
Cellulose Microcrystalline	LC50 (Trout family (Salmonidae), 96 h): > 100% Saturated solution.
Losartan Potassium	LC50 (Rainbow Trout, 96 h): > 929 mg/l LC50 (Fathead minnow (Pimephales promelas), 48 h): > 1,000 mg/l
Starch	No data available.
Titanium Dioxide	LC50 (Mummichog (Fundulus heteroclitus), 96 h): > 1,000 mg/l mortality. LC50 (Mummichog (Fundulus heteroclitus), 72 h): > 1,000 mg/l mortality. LC50 (Mummichog (Fundulus heteroclitus), 48 h): > 1,000 mg/l mortality. LC50 (Mummichog (Fundulus heteroclitus), 24 h): > 1,000 mg/l mortality.

Chronic Toxicity(Fish):

Name	Test results
Cellulose Microcrystalline	No data available.
Losartan Potassium	NOEC (Fathead minnow (Pimephales promelas), 32 d): 10 mg/l No effects seen up to highest concentration tested (reported).
Starch	No data available.
Titanium Dioxide	No data available.

Acute toxicity(Aquatic invertebrates):

Name	Test results
Cellulose Microcrystalline	LC50 (Water Flea, 48 h): > 100 % Saturated solution.
Losartan Potassium	LC50 (Water Flea, 48 h): 331 mg/l
Starch	No data available.
Titanium Dioxide	EC 50 (Water flea (Daphnia magna), 48 h): > 1,000 mg/l Intoxication

Chronic Toxicity(Aquatic invertebrates):

Name	Test results
Cellulose Microcrystalline	No data available.
Losartan Potassium	NOEC (Water flea (Daphnia magna), 21 d): 100 mg/l No effects seen up to highest concentration tested (reported).
Starch	No data available.
Titanium Dioxide	No data available.

Acute toxicity(Aquatic plants):

Name	Test results
Cellulose Microcrystalline	EC 50 (Algae, algal mat (Algae), 96 h): > 100% Saturated solution.
Losartan Potassium	NOEC (Blue-green algae (Microcystis aeruginosa), 10 d): 949 mg/l (growth rate) NOEC (Green algae (Selenastrum capricornutum), 10 d): 143 mg/l
Starch	No data available.
Titanium Dioxide	No data available.

Persistence and degradability:	Expected to biodegrade slowly. The active pharmaceutical ingredient undergoes rapid photolysis when dissolved in water under natural light conditions.
Bioaccumulative potential:	Will not bio-accumulate.
Mobility:	Active pharmaceutical ingredient is soluble in water.

13 DISPOSAL CONSIDERATIONS

Disposal Methods:	Do not allow runoff to sewer, waterway or ground. Discharge, treatment, or disposal may be subject to national, state, or local laws.
Measures for Avoidance and Recovery:	Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14 TRANSPORT INFORMATION**DOT**

Not regulated.

IMDG - International Maritime Dangerous Goods Code

Not regulated.

IATA - International Air Transport Association

Not regulated.

15 REGULATORY INFORMATION**US Regulations**

- **CERCLA Hazardous Substance List (40 CFR 302.4):**
None
- **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**
None
- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**
None

SARA Title III

- **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**
None
- **Section 313 Toxic Release Inventory (40 CFR 372):**
None present or none present in regulated quantities.

State Regulations

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**
No ingredient regulated by CA Prop 65 present.

• **Massachusetts Right-To-Know List:**

Cellulose Microcrystalline	Listed
Starch	Listed
Titanium Dioxide	Listed
SILICON DIOXIDE	Listed

• **New Jersey Right-To-Know List:**

Titanium Dioxide	Listed
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• **Pennsylvania Right-To-Know List:**

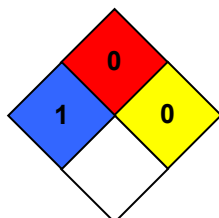
Cellulose Microcrystalline	Listed
Starch	Listed

16 OTHER INFORMATION

OTHER INFORMATION

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

NFPA Hazard ID



Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

Revision Information:

Not relevant.

Issue Date:

12.02.2014

Disclaimer:

This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.