SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product name: Hydrochlorothiazide and Lisinopril Tablets

SDS No: P00000020069

Synonyms, Trade Names:
PRINZIDE, VIVATEC Comp., CARACE Plus, CORIC Plus, NOVAZYD, VIVAZID, IRUZID, MK-0521

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:	
Color:	Various
Form :	Tablets
Odor:	Odorless
Signal words	WARNING!
Potential Health Effects:	
General	No specific hazard with intact tablets or capsules. Avoid prolonged or repeated breathing of dust. Wash thoroughly after handling.
Potential Physical / Chemical Effects:	None under normal conditions.
Inhalation:	No data available.
Skin:	Slightly irritating to the skin.
Eye:	Slightly irritating to the eyes.
Ingestion:	Intended route for clinical use. Practically non-toxic if swallowed.
Signs and Symptoms:	Pre-existing medical conditions which may be aggrevated by exposure include: kidney problems, hypoglycemia in diabetes treated with oral antidiabetic agents or insulin may increase potassium levels in the blood.
Routes of Exposure:	Inhalation

Target Organs: Kidney, Blood

OSHA Regulatory Status This product is hazardous according to OSHA 29CFR 1910.1200.

Environment: Not expected to be harmful to aquatic organisms.

OTHER INFORMATION No additional information

3 COMPOSITION / INFORMATION ON INGREDIENTS

General information: The formulation for this product is 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
CALCIUM PHOSPHATE DIBASIC	7757-93-9	40 - 70%
STARCH	9005-25-8	15 - 40%
LISINOPRIL	83915-83-7	9.0%
Hydrochlorothiazide	58-93-5	8.4%

* 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:
Treatment: Treat supportively and symptomatically.

5 FIRE-FIGHTING MEASURES

Extinguishing media: Water spray, fog, CO2, 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. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures.

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
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)
LISINOPRIL	TWA	0.04 mg/m3	Merck Occupational Exposure Band (OEB) or Wipe Test criteria
	Wipe Test	0.4 mg/100 cm2	Merck Occupational Exposure Band (OEB) or Wipe Test criteria
	TWA	OEB Cat.3	Merck Occupational Exposure Band (OEB) or Wipe Test criteria
Hydrochlorothiazide	TWA	0.1 mg/m3	Merck Occupational Exposure Band (OEB) or Wipe Test criteria
	Wipe Test	---	Merck Occupational Exposure Band (OEB) or Wipe Test criteria

OEB Category 3 is an internal Merck control band and corresponds to the 8-hour TWA (time-weighted average) and concentration of 10 - <100 µg / m3. Refer to recommendations below. OEB Category 2 is an internal Merck control band and corresponds to the 8-hour TWA (time-weighted average) and concentration of 0.1 - <1.0 mg / m3. Refer to recommendations below.

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
Color: Various
Odor: Odorless

Other information:
VOC Content: 0 g/l

10 STABILITY AND REACTIVITY

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.

Specified substance(s):

Acute Toxicity (Oral);

Name	Test results
LISINOPRIL	LD 50 (Rat): > 20,000 mg/kg LD 50 (Mouse): > 20,000 mg/kg
Hydrochlorothiazide	LD 50 (Rat): > 10,000 mg/kg LD 50 (Mouse): > 10,000 mg/kg LD 50 (Mouse): 3,080 mg/kg

Inhalation: No data available.

Ingestion: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/eye No data available.

irritation:

Respiratory sensitizer/Skin sensitizer: No data available.

Carcinogenicity: No data available.

Mutagenesis: No data available.

Reproductive toxicity: No data available.

Other Effects: No additional information

12 ECOLOGICAL INFORMATION

Ecotoxicity: No data available.

Specified substance(s):

Acute toxicity(Fish):

Name	Test results
Hydrochlorothiazide	LC 50 (Fathead Minnow, 48 h): > 500 mg/l

Acute toxicity(Aquatic invertebrates):

Name	Test results
LISINOPRIL	LC 50 (Water flea (Daphnia magna), 48 h): 20,000 mg/l
Hydrochlorothiazide	LC 50 (Water flea (Daphnia magna), 46 h): > 500 mg/l

Persistence and degradability: The subject product is expected to biodegrade and is not expected to persist for long periods in an aquatic environment.

Bioaccumulative potential: The active pharmaceutical ingredient's potential to bioaccumulate is low.

Mobility: Expected to partition to 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.

14 TRANSPORT INFORMATION

DOT - Department of Transportation
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:**
  STARCH Listed

- **New Jersey Right-To-Know List:**
  No ingredient regulated by NJ Right-to-Know Law present.

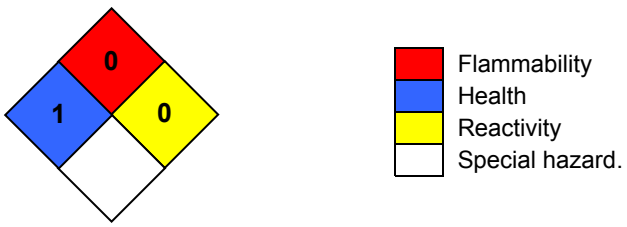
- **Pennsylvania Right-To-Know List:**
  STARCH Listed

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: 22.07.2011
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.