

# MATERIAL SAFETY DATA SHEET

## **Moexipril HCl / HCTZ Tablets (15mg/12.5mg, 15mg/25mg, and 7.5mg/12.5mg)**

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### **SECTION 1: PRODUCT IDENTIFICATION**

PRODUCT NAME: Moexipril HCl / HCTZ Tablets (15mg/12.5mg, 15mg/25mg, and 7.5mg/12.5mg)  
COMMON NAME: Moexipril HCl / HCTZ Tablets  
CHEMICAL NAME: Moexipril HCl, Hydrochlorothiazide  
SYNONYMS: NA  
CHEMICAL FORMULA:  $C_{27}H_{34}N_2O_7HCl$  (Moexipril HCl),  $C_7H_8ClN_3O_4S_2$  (Hydrochlorothiazide)  
CHEMICAL FAMILY: ACE Inhibitor, Antihypertensive, Diuretic

### **SECTION 2: COMPOSITION AND INGREDIENTS**

<b>CHEMICAL NAME</b>	<b>CAS#</b>	<b>%</b>	<b>OSHA PEL</b>	<b>ACGIH TLV</b>
Moexipril HCl	82586-52-5	<10	NE	NE
Hydrochlorothiazide USP	58-93-5	<5	NE	NE
Lactose Monohydrate NF	64044-51-5	>25	NE	NE
Crospovidone XL NF	9003-39-8	<10	NE	NE
Povidone USP	9003-39-8	<5	NE	NE
Magnesium Oxide USP	01309-48-4	<5	15 mg/m <sup>3</sup>	10 mg/m <sup>3</sup>
Opadry (color)	Mixture	<5	10 mg/m <sup>3</sup>	5 mg/m <sup>3</sup>
Colloidal Silicon Dioxide NF	112945-52-5	<1	6 mg/m <sup>3</sup>	10 mg/m <sup>3</sup>
Magnesium Stearate NF	00557-04-0	<1	15 mg/m <sup>3</sup>	10 mg/m <sup>3</sup>

NE = Not Established, Specific amounts are considered proprietary information.

### SECTION 3: HAZARDS IDENTIFICATION

Symptoms of Overexposure by Route of Exposure:

Ingestion: Cough, diarrhea, flushing, rash, and muscle pain. Some individuals may experience swelling of the face, extremities, lips, tongue, glottis, and/or larynx. Swelling of the tongue or larynx may result in difficult breathing. Overdosage results primarily in hypotension which could lead to dizziness, lightheadedness, and fainting. Accidental ingestion of normal dosages (no more than 4 tablets in 24 hours for adults) is not likely to cause significant adverse health effects.

Inhalation: Dust may cause irritation, coughing, or difficulty breathing. Under normal conditions of use, inhalation is not expected to occur.

Eyes: May cause irritation. Under normal conditions of use, eye contact is not expected to occur.

Skin: May cause irritation.

Medical Conditions Aggravated by Long-Term Exposure: Congestive heart failure, ischemic heart disease (low blood supply to the heart), aortic stenosis (narrow aortic valve which causes decreased heart function, characterized by faint pulse in hands and feet, exercise intolerance, and/or chest pain), cerebrovascular disease (disease of the blood vessels of the brain.), anuria, hyperuricemia, impaired liver or kidney function, hypercalcemia, and Addison's disease.

Other Comments: **Pregnancy Category D**. When used during the second and third trimesters of pregnancy, ACE inhibitors can cause injury and even death to the developing fetus.

### SECTION 4: FIRST AID MEASURES

Skin Exposure: Thoroughly wash with mild soap and water if irritation develops.

Eye Exposure: Immediately flush eye with copious amounts of water. Seek medical attention if irritation develops.

Inhalation: Inhalation exposure is not expected to occur. In the case of exposure to excessive levels of dust, remove to fresh air. Get medical attention immediately if cough or other symptoms develop.

Ingestion: Seek medical attention. Do not attempt to induce vomiting unless directed by medical personnel. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious.

NOTE TO PHYSICIANS: Although rare, some individuals may experience significant edema of the face, tongue, glottis, or larynx when treated with ACE inhibitors. Appropriate treatment should be administered promptly.

### SECTION 5: FIRE / EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES

Flash Point: NE

Autoignition Temperature: NE

Flammable Limits (in air by volume, %): Lower: NE Upper: NE

Fire Extinguishing Equipment: Water spray, dry powder, CO<sub>2</sub>, or foam as suitable for type of surrounding fire.

Unusual Fire and Explosion Hazards: Decomposition emits toxic fumes of SO<sub>x</sub>, NO<sub>x</sub>, and Cl<sup>-</sup>.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

**Special Fire Fighting Procedures:** For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by the DOT *Emergency Response Guidebook*, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

**Spill and Leak Response:** Clean up material and place in an appropriate disposal container. Avoid runoff into storm sewers and ditches which lead to waterways. Avoid breaking tablets and creating dust. Dispose of in accordance with federal, state and local regulations.

## SECTION 7: HANDLING AND STORAGE

**Work and Hygiene Practices:** As with all chemicals, avoid getting this product on you or in you. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling. Avoid breathing dust. Avoid contact with eyes, skin, and clothing.

**Handling:** No not break or crush tablets. Avoid creating dust.

**Storage:** Store at controlled room temperature 15°C to 30°C (59°F to 86°F). Avoid excessive moisture.

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

**Engineering Controls:** In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels at a minimum. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

**Ventilation:** No special ventilation is required under normal conditions of use of the finished product.

**Respiratory Protection:** No special requirements under normal conditions, avoid breathing excessive dust.

**Eye Protection:** Safety glasses are recommended.

**Hand Protection:** Gloves are recommended.

**Body Protection:** No special requirements under normal conditions of use.

**Product Preparation Instructions for Medical Personnel:** Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

## SECTION 9: PHYSICAL / CHEMICAL PROPERTIES

Boiling Point:	ND	Vapor Pressure:	ND
Melting/Freezing Point:	ND	pH:	ND
Water Solubility:	Soluble	Water Reactive:	No
Specific Gravity (Water =1):	ND	Evaporation Rate (Butyl acetate = 1):	ND
Appearance/Odor:	White or yellow, oval, biconvex tabs.		

ND = No Data

**SECTION 10: STABILITY AND REACTIVITY**

Stability:	Stable under labeled storage conditions.
Incompatible Materials:	None
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	Excessive moisture, heat.
Hazardous Decomposition or Byproducts:	Heating to decomposition may produce toxic fumes including carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), sulfur oxides (SO <sub>x</sub> ), and halogenated compounds.

**SECTION 11: TOXICOLOGICAL INFORMATION**Toxicity Data:

Oral LD<sub>50</sub> Rat = 1175 mg/kg (Hydrochlorothiazide USP)

Oral LD<sub>50</sub> Rat = 3000mg/kg (Moexipril HCl)

Carcinogenicity: Not listed as a carcinogen.

Reproductive effects: This material is classified as Pregnancy Category D. When used during the second and third trimesters of pregnancy, ACE inhibitors, including Moexipril, can cause injury and even death to the developing fetus.

Mutagenicity: Not expected to be mutagenic.

Chronic health effects: May cause hypersensitization.

**SECTION 12: ECOLOGICAL INFORMATION**

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: Ecological tests results for Moexipril HCl revealed that the compound is non-toxic to invertebrate and microbial organisms.

Effect of Chemicals on Aquatic Life: No specific information is available on the effects of this product on aquatic life.

**SECTION 13: WASTE DISPOSAL**

Preparing Wastes for Disposal: Dispose of in accordance with local, state, and federal regulations.

**SECTION 14: TRANSPORTATION INFORMATION**

Transportation and shipping of this product is not restricted.

**SECTION 15: REGULATORY INFORMATION****U.S. REGULATIONS:**

U.S. SARA Reporting Requirements: 311/312 Hazard Categories: Immediate Health, 313 Reportable Ingredients: None

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

**SECTION 16: OTHER INFORMATION**

## DEFINITIONS OF ABBREVIATIONS USED:

ACGIH:	American Conference of Governmental Industry Hygienists
CAS:	Chemical Abstract Service
IARC:	International Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health Level
LC <sub>50</sub> :	Medial Lethal Concentration
LD <sub>50</sub> :	Medial Lethal Dose
MSHA:	Mine Safety and Health Administration
N/A:	Not Available
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limit
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Value
TWA:	Time Weighted Average

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