

MATERIAL SAFETY DATA SHEET

Moexipril 7.5 mg Tablets

Paddock Laboratories, Inc.
3940 Quebec Avenue North
Minneapolis, MN 55427

Emergency Assistance:
CHEMTREC® (24-hour) 1-800-424-9300

Tel: (763) 546-4676

Paddock Technical Assistance: 1-800-328-5113

Creation Date: 23 August 2004

Revision Date: 23 August 2004

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: Moexipril 7.5 mg Tablets
COMMON NAME: Moexipril 7.5 mg Tablets
CHEMICAL NAME: Moexipril HCl
SYNONYMS: NA
CHEMICAL FORMULA: $C_{27}H_{34}N_2O_7HCl$
CHEMICAL FAMILY: ACE Inhibitor, Antihypertensive

SECTION 2: COMPOSITION AND INGREDIENTS

| CHEMICAL NAME | CAS# | % w/w | OSHA PEL | ACGIH TLV | IDLH |
|--|-------------|-------|----------------------|----------------------|------|
| Moexipril HCl | 82586-52-5 | <10 | NE | NE | NE |
| Magnesium Oxide, USP | 01309-48-4 | <10 | 15 mg/m ³ | 10 mg/m ³ | NE |
| Lactose Monohydrate, NF | 64044-51-5 | >50 | NE | NE | NE |
| Povidone K-29 | 9003-39-8 | <10 | NE | NE | NE |
| Crospovidone XL, NF | 9003-39-8 | <10 | NE | NE | NE |
| Colloidal Silicon Dioxide, NF (Aerosil 200) | 112945-52-5 | <10 | 6 mg/m ³ | 10 mg/m ³ | NE |
| Magnesium Stearate, NF | 00557-04-0 | <10 | 15 mg/m ³ | 10 mg/m ³ | NE |
| Opadry | Mixture | <10 | 10 mg/m ³ | 5 mg/m ³ | NE |

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

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Moexipril 7.5 mg tablets are light beige, round, biconvex, film coated tablets with "110" debossing on one side and scored on the other side of the tablet. The ingredients listed are non-hazardous.

Symptoms of Overexposure by Route of Exposure: Overexposure by ingestion includes cough, diarrhea, and 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.

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.

| | | | |
|------------------------------|---|---------------------------------------|----|
| 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: | Light beige, round, biconvex, film coated tablets with "110" debossing on one side and scored on the other side of the tablet. No odor. | | |

ND = No Data

SECTION 10: STABILITY AND REACTIVITY

| | |
|---------------------------|--|
| Stability: | Stable under labeled storage conditions. |
| Incompatible Materials: | None Known |
| Hazardous Polymerization: | Will not occur. |
| Conditions to Avoid: | Protect from excessive moisture. Store between 15°C and 30°C (59°F to 86°F). |

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Moexipril HCl 7.5 mg tablets.

Oral LD₅₀ Rat = >2000mg/kg
(Povidone K-29)

Oral LD₅₀ Rat = >100000 mg/kg
(Crospovidone XL, NF)

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC or OSHA.

Irritancy of Product: During normal use of product no eye contact should occur. Avoid exposure to excessive dust.

Sensitization to the Product: Not Known.

Reproductive Toxicity Information: This material is classified as a Pregnancy Category B (Risk to Fetus Cannot be Ruled-Out). 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: ND

Embryotoxicity/Teratogenicity/Reproductive Toxicity: ND

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

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 Moexipril on aquatic life.

SECTION 13: WASTE DISPOSAL

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

SECTION 14: TRANSPORTATION INFORMATION

This Material is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

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 (RO): Not applicable

U.S. TSCA Inventory Status: Moexipril HCl is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore 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.

ANSI Labeling (Based on 129.1. Provided to Summarize Occupational Exposure Hazards):

WARNING! Moexipril HCl 7.5 mg tablets should be administered under the supervision of a qualified physician.

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 ₅₀ : | Medial Lethal Concentration |
| LD ₅₀ : | 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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NE = Not Established, Specific amounts are considered proprietary information.

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Moexipril 15 mg tablets are dark beige, round, biconvex, film coated tablets with "PAD" and "112" debossing on one side and scored on the other side of the tablet. The ingredients listed are non-hazardous.

Symptoms of Overexposure by Route of Exposure: Overexposure by ingestion includes cough, diarrhea, and 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 TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.

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: | Dark beige, round, biconvex, film coated tablet, with "PAD" and "112" debossing on one side and scored on the other side of the tablet. | | |

ND = No Data

SECTION 10: STABILITY AND REACTIVITY

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|---------------------------|--|
| Stability: | Stable under labeled storage conditions. |
| Incompatible Materials: | None Known |
| Hazardous Polymerization: | Will not occur. |
| Conditions to Avoid: | Protect from excessive moisture. Store between 15°C and 30°C (59°F to 86°F). |

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Sensitization to the Product: Not Known.

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UN Identification Number: Not applicable

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ANSI Labeling (Based on 129.1. Provided to Summarize Occupational Exposure Hazards):

WARNING! Moexipril HCl 15 mg tablets should be administered under the supervision of a qualified physician.

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| 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 ₅₀ : | Medial Lethal Concentration |
| LD ₅₀ : | 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 |