Monarch Pharmaceuticals, Inc.
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MATERIAL SAFETY DATA SHEET

While we believe the information provided herein is accurate and current, Monarch Pharmaceuticals makes no representations or warranties, either expressed or implied, and assumes no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information.

SECTION I MATERIAL IDENTIFICATION

PRODUCT NAME: Altace® capsules

DATE OF ISSUE: 06/19/03

FORMULA: $C_{23}H_{32}N_2O_5$

SUPERSEDES: N/A

NDC#:
61570-110-01 (1.25mg 100's)
61570-110-56 (1.25mg Unit Dose)
61570-111-05 (2.5mg 500's)
61570-111-01 (2.5mg 100's)
61570-111-56 (2.5mg Unit Dose)
61570-112-05 (5mg 500's)
61570-112-01 (5mg 100's)
61570-112-56 (5mg Unit Dose)
61570-120-05 (10mg 500's)
61570-120-01 (10mg 100's)
61570-111-10 (2.5mg 1000's)
61570-120-10 (10mg 1000's)
61570-111-50 (2.5mg 5000's)
61570-112-50 (5mg 5000's)
61570-112-10 (5mg 1000's)

REVISION: N/D

SYNONYMS: Ramipril

MANUFACTURING DIVISION:	ADDRESS	PERSON TO CONTACT	PHONE #
.	501 Fifth Street Bristol, TN 37620	Bill Smith	423-989-8042

SECTION II INGREDIENT (S)

		EXPOSURE LIMITS/GUIDELINES			
CAS#	**INGREDIENT NAME**	**OSHA PEL**	**ACGIH TLV**	**OTHER**	**LISTED AS CARCINOGEN**
87333-19-5	Ramipril	N/D	N/D	N/D	N/D
N/D	Pregelatinized starch	N/D	N/D	N/D	N/D
N/D	Gelatin	N/D	N/D	N/D	N/D
N/D	Titanium dioxide	N/D	N/D	N/D	N/D
N/D	Yellow Iron Oxide (1.25mg)	N/D	N/D	N/D	N/D
N/D	D&C Yellow #10 (2.5mg)	N/D	N/D	N/D	N/D
N/D	FD&C Red #40 (2.5mg)	N/D	N/D	N/D	N/D
N/D	FD&C Blue #1 (5mg)	N/D	N/D	N/D	N/D
N/D	FD&C Red #40 (5mg)	N/D	N/D	N/D	N/D
N/D	FD&C Blue #1 (10mg)	N/D	N/D	N/D	N/D

SECTION III PHYSICAL AND CHEMICAL DATA

PHYSICAL STATE: capsule

APPEARANCE: 1.25mg; yellow, hard gelatin capsules
2.5mg; orange, hard gelatin capsules
5mg; red, hard gelatin capsules
10mg; blue, hard gelatin capsules

CHARACTERISTIC ODOR: N/A

SPECIFIC GRAVITY: N/D

SOLUBILITY IN WATER: soluble

pH: N/D

SECTION IV FIRE AND EXPLOSION DATA

FLASH POINT AND METHOD: N/D

EXTINGUISHING MEDIUM: N/D

SPECIAL FIRE FIGHTING PROCEDURES: Wear full bunker gear, including SCBA, when responding to fires involving facilities where pharmaceutical products are stored.

HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS: none

SECTION V CHEMICAL REACTIVITY DATA

STABILITY: chemically stable

INCOMPATIBILITY: ND

HAZARDOUS POLYMERIZATION: none

HAZARDOUS DECOMPOSITION OF BYPRODUCTS: N/D

CONDITIONS TO AVOID: none

SECTION VI HEALTH HAZARD INFORMATION

ROUTE OF ENTRY: oral

HEALTH HAZARD: Most common manifestation of overexposure would be hypotension. Side effects would include headache, dizziness, fatigue, nausea/vomiting.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Any existing hypersensitivity to Altace and angioneurotic edema.

TOXICITY INFORMATION: Oral LD50 (rat): >10,000mg/kg (ramipril)
Oral LD50 (mouse): >10,500mg/kg (ramipril)
Oral LD50 (dog): >1,000mg/kg (ramipril)

CARCINOGENIC EFFECTS: Two year carcinogenicity studies in rats and mice were negative.

MUTAGENIC: Data based on ramipril:

Ames Test: Negative
Unscheduled DNA Synthesis: Negative
Mammalian Point Mutation: Negative
Chromosome Abberration Test: Negative
Micronucleus Test: Negative

TERATOGENIC: Data based on ramipril:

When pregnant rat, rabbit and monkey females were dosed to maternally toxic levels, the results were: Reduced Fertility: Negative; Selective Embryo/Fetal Toxicity: Negative; Developmental Delay: Negative. In the rat studies, evidence of renal effects in the F1 generation pups were observed.

In therapeutic doses, angiotensin converting enzyme (ACE) inhibitor drugs can cause fetal and neonatal morbidity and mortality when administered to pregnant women. When ACE inhibitors have been used during the second and third tri-mesters of pregnancy, there have been reports of neonatal hypotension, renal failure, skull hypoplasia and death.

(For further information see current package insert)

SECTION VII FIRST AID INFORMATION

EYES: none **SKIN:** none **INHALATION:** none

INGESTION: Overdose: If conscious, give water to drink and induce vomiting. Never give anything by mouth to an unconscious person. Immediately seek medical attention.
NOTE TO PHYSICIANS: Because the hypotensive effect of Altace is achieved through vasodilation and effective hypovolemia, it is reasonable to treat Altace overdose by infusion of normal saline solution.

REGULATED EXPOSURE LIMITS: N/D

SECTION VIII SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION: none **PROTECTIVE GLOVES:** none

VENTILATION: none **EYE PROTECTION:** none

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: none

SECTION IX SPILL, LEAK, AND DISPOSAL PROCEDURES

ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED: Spilled capsules should be picked up and disposed of as pharmaceutical waste.

WASTE DISPOSAL METHOD: Bulk quantities of waste capsules should be incinerated according to local, state and federal regulations or the authority having jurisdiction.

SECTION X SPECIAL PRECAUTIONS

STORE AS STATED IN PRODUCT LABELING: Store at controlled room temperature (59 to 86 degrees F).

OTHER PRECAUTIONS: Dispense in well-closed container with safety closure.

N/D=Not determined N/A=Not applicable

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company regarding the most current MSDS available.