InvaGen Pharmaceuticals, Inc.

SAFETY DATA SHEET

Fosinopril Sodium Tablets, USP

1. IDENTIFICATION

Manufacturer:

InvaGen Pharmaceuticals Inc.
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Fosinopril Sodium Tablets, USP

Chemical Family: Alkali metal salt

Synonym(s): No data available.

Chemical Name: (4S)-4-Cyclohexyl-1-[(R)-[(S)-1-hydroxy-2-methylpropoxy](4-phenylbutyl)phosphinyl] acetyl-L-proline propionate (ester), sodium salt

Trade Name(s): Fosinopril Sodium Tablets, USP 10 mg, 20 mg and 40 mg.

Therapeutic Category: Antihypertensive (ACE inhibitor)

Molecular formula: $C_{30}H_{45}NNaO_7P$ **Molecular Weight:** 585.64

2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement:
Each Fosinopril Sodium Tablets intended for oral administration contains Fosinopril Sodium, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Note:

USE IN PREGNANCY

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Fosinopril Sodium Tablet should be discontinued as soon as possible.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact Tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure: ACE inhibitors: Angioedema, Active alcoholism, Severe auto-immune disease, Cerebrovascular or coronary insufficiency, Diabetes mellitus, Kidney transplant, Impaired liver or kidney function, Hyperkalemia, Bone marrow depression, Volume depletion caused by severe dietary sodium restriction or dialysis.

Carcinogenicity: Fosinopril Sodium - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS #	Concentration %		
		10 mg	20 mg	40 mg
Fosinopril Sodium, USP	88889-14-9	≈12.5 %	≈12.5 %	≈12.5 %
Excipients	NA	≈87.5 %	≈87.5 %	≈87.5 %

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.
* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:
In animals and humans, fosinopril sodium is hydrolyzed by esterases to the pharmacologically active form, fosinopril at, a specific competitive inhibitor of angiotensin-converting enzyme (ACE).

ACE is a peptidyl dipeptidase that catalyzes the conversion of angiotensin l to the vasoconstrictor substance, angiotensin II. Angiotensin II also stimulates aldosterone secretion by the adrenal cortex. Inhibition of ACE results in decreased plasma angiotensin II, which leads to decreased vasopressor activity and to decrease aldosterone secretion. The latter decrease may result in a small increase of serum potassium.

Overdose Treatment:
Oral doses of fosinopril at 2600 mg/kg in rats were associated with significant lethality. Human overdoses of fosinopril have not been reported, but the most common manifestation of human fosinopril over dosage is likely to hypotension.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO2, dry chemical or alcohol resistant foam.

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 firefighting procedures.

Environmental precautions: Do not release in to 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. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

10 mg Tablets	White, round, biconvex partially scored tablets de-bossed with “IG” on one side and “200” on other side.
20 mg Tablets	White, round, biconvex tablets de-bossed with “IG” on one side and “201”on other side.
40 mg Tablets	White, round, biconvex tablets de-bossed with “IG” on one side and “202”on other side.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers, Strong Bases and Strong Acids.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate irritating gases or vapors.

11.TOXICOLOGICAL INFORMATION

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

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.

Carcinogenesis:
No evidence of carcinogenic effect was found when fosinopril was given in the diet to mice and rats for up to 24 months at doses up to 400 mg/kg/day.

Mutagenesis:
Neither Fosinopril nor the active fosinoprilat was mutagenic in the Ames microbial mutagen test, the mouse lymphoma forward mutation assay, or a mitotic gene conversion assay. Fosinopril was also not genotoxic in a mouse micronucleus test in vivo and a mouse bone marrow cytogenetic assay in vivo.

Impairment of Fertility:
There were no adverse reproductive effects in male and female rats treated with 15 or 60 mg/kg daily. On a body weight basis, the high dose of 60 mg/kg is about 38 times the maximum recommended human dose. On a body surface area basis, this dose is 6 times the maximum recommended human dose. There was no effect on pairing time prior to mating in rates until a daily dose of 240 mg/kg, a toxic dose, was given; at this dose, a slight increase in pairing times was observed. On a body weight basis, this dose is 150 times the maximum recommended human dose. On a body surface area basis, this dose is 24 times the maximum recommended human dose.

Other information:
Medically important adverse effects reported with ACE inhibitors include: Cardiac arrest; eosinophilic pneumonitis; neutropenia/agranulocytosis, pancytopenia, anemia (including

hemolytic and aplastic), thrombocytopenia; acute renal failure; hepatic failure, jaundice (hepatocellular or cholestatic); symptomatic hyponatremia; bullous pemphigus, exfoliative dermatitis; a syndrome which may include: arthralgia/arthritis, vasculitis, serositis, myalgia, fever, rash or other dermatologic manifestations, a positive ANA, leukocytosis, eosinophilia, or an elevated ESR.

12.ECOLOGICAL INFORMATION

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

Ecotoxicity Effects:
Acute toxicity to Fish: No data available.
Acute toxicity to Aquatic Invertebrates: No data available.
Toxicity to Aquatic Plants: No data available.
Bioaccumulation: No data available.
Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and 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: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of InvaGen Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

CERLA Hazardous Substance List (40 CFR 302.4): None
TSCA : None
SARA Title III
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None
Section 313 Toxic Release Inventory (40 CFR 372): None

16.OTHER INFORMATION

SDS Sections Revised:
Revision 01: Sections 1 to 16 contain revisions to comply with 29 CFR 1910.1200(g) and Appendix D**.**

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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