Fosinopril sodium

sc-205702

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Fosinopril sodium

STATEMENT OF HAZARDOUS NATURE
CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA


SUPPLIER
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ChemWatch
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SYNONYMS
C30-H46-N-O7-P.Na, Monopril, SQ-28555, "sodium salt of:", (4S)-4-cyclohexyl-1[(((RS)-1-hydroxy-2-methylpropoxy)(4-phenylbutyl)-, "phosphinyl)acetyl]-L-proline propionate", "(2alpha, 4beta)-4-cyclohexyl-1-[(2-methyl-1-(1-oxopropoxy)propoxy)-", (4-phenylbutyl)phosphinyl)acetyl]-L-proline, fosenopril, antihypertensive, "ACE inhibitor", "angiotensin converting enzyme inhibitor"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	2		

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW

RISK

Irritating to eyes.
May cause SENSITISATION by skin contact.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be damaging to the health of the individual.
■ ACE inhibitors are fairly safe and serious overdoses are rare. Overdoses may cause low blood pressure, increased heart rate and reversible kidney failure.
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EYE

■ There is evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation. Severe inflammation may be expected with pain.
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SKIN

■ The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
■ Open cuts, abraded or irritated skin should not be exposed to this material.
■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
There is some evidence that inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population.
There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.
Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, on the basis that similar materials tested in appropriate animal studies provide some suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects.
Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.
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ACE inhibitors may aggravate kidney and collagen vascular disorders. They may cause injury and death to the fetus late in pregnancy.
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Exposure to small quantities may induce hypersensitivity reactions characterized by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic edema), running nose (rhinitis) and blurred vision . Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur.
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Respiratory sensitization may result in allergic/asthma like responses; from coughing and minor breathing difficulties to bronchitis with wheezing, gasping.
Fosinopril sodium is foetotoxic in rats and rabbits at very high doses; it was not mutagenic in several different tests or carcinogenic in a chronic bioassay.
In a two-year study involving mice and rats at doses up to 400 mg/kg daily, there was no evidence of carcinogenicity. Neither the sodium salt or diacid were 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 cytogenic assay in vivo. In the Chinese hamster ovary cell cytogenic assay, fosinopril increased the frequency of chromosomal aberrations when tested without metabolic activation at a concentration toxic to the cell. There were no increases in chromosomal aberrations at lower drug concentrations without metabolic activation or at any concentration with metabolic activation.
There were no adverse reproductive effects in male and female rats treated with 15-60 mg/kg daily. There was no effect on pairing time in rats until a daily dose of 240 mg/kg, a toxic dose, was given; at this dose, a slight increase in pairing times occurred. In rats fosinpril sodium was foetotoxic at doses of 25 mg/kg/day and higher (days 7-16 gestation) and in rabbits at doses of 10 mg/kg/day. These doses were also toxic to the dams.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
fosinopril sodium	88889-14-9	>98

Section 4 - FIRST AID MEASURES

SWALLOWED
· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

EYE
■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN
■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED
· If dust is inhaled, remove from contaminated area. · Encourage patient to blow nose to ensure clear passage of breathing. · If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN
■ Supportive care should be given in overdose. The patient should be given adequate fluids, if necessary with IV fluids, to maintain a satisfactory blood pressure and a good urine output.
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Oral administration of the sodium salt is followed by slow absorption with an average 36% absorbed. The primary site of absorption is the proximal small intestine. In healthy subjects and renally impaired patients, conversion to the diacid is rapid and complete. Hepatic impairment does not appear to substantially reduce the extent of hydrolysis although the rate may be slowed. Metabolites include the glucuronide and the p-hydroxy-metabolite of fosinopril diacid. The diacid is not biotransformed after intravenous administration, it is thought that fosinopril (the prodrug) may be the substrate for glucuronide and p-hydroxy metabolites. Clearance of fosinopril diacid by haemodialysis and peritoneal dialysis averages 2% and 7% respectively, of urine clearances. Studies in animals indicate that fosinopril and the diacid do not cross the blood brain barrier. Fosinopril diacid was detectable but not quantifiable in breast milk.
The material may cause a worsening of renal function in individuals with a history of renal disease. It may also produce a chronic cough. Prior to working with fosinopril, personnel should be questioned to determine a history of kidney disease. If exposure exceeds the exposure guideline, personnel should be monitored for low blood pressure, cough, proteinuria, renal function and complete blood count. Appropriate medical counseling/ recommendations should be provided to the employee based on the outcome of the medical evaluation.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	>2.8x10(-8)
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA
· Water spray or fog.
· Foam.

FIRE FIGHTING
· Alert Emergency Responders and tell them location and nature of hazard.
· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS
· Combustible solid which burns but propagates flame with difficulty.
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), nitrogen oxides (NOx), phosphorus oxides (POx), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.
May emit corrosive fumes.
Dusts with Minimum Ignition Energies (MIEs) ranging between 20 and 100 mJ may be sensitive to ignition. They require that:
· plant is grounded
· personal might also need to be grounded
· the use of high resistivity materials (such as plastics) should be restricted or avoided during handling or in packaging
The majority of ignition accidents occur within or below this range.
Dust Explosion Hazard Class 2Dusts fall into one of three Kst* classes. Class 1 dusts; Kst 1-200 m3/sec; Class 2 dusts; 201-299 m3/sec.
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Explosion data relative to static discharge:

Explosion Severity Factor (Kst): 230 bar.m/s
Explosion Class: Kst-2
Charge Decay Time: 1.1 hours
Minimum ignition energy: 20-30 mJ
Resistivity: 5.3 ee 13 ohm.m
The material exhibits strong explosion characteristics if ignited as a dust cloud. Material is highly susceptible to accumulating static charges during processing and uncontrolled static discharge may result in igniting a dust cloud under certain conditions due to the low minimum ignition energy.

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids,chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:
Chemical goggles.
Gloves:
Respirator:
Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS
· Clean up waste regularly and abnormal spills immediately.
· Avoid breathing dust and contact with skin and eyes.
· Wear protective clothing, gloves, safety glasses and dust respirator.
· Use dry clean up procedures and avoid generating dust.
· Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
· Dampen with water to prevent dusting before sweeping.
· Place in suitable containers for disposal.
MAJOR SPILLS
■ Moderate hazard.
· CAUTION: Advise personnel in area.
· Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

· Avoid all personal contact, including inhalation.
· Wear protective clothing when risk of exposure occurs.
Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
· Do NOT cut, drill, grind or weld such containers.
· In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

■ Glass container.
· Packaging as recommended by manufacturer.
· Check that containers are clearly labelled.
· Tamper-proof containers.
· Polyethylene or polypropylene containers.
· Metal drum with sealed plastic liner.

STORAGE REQUIREMENTS

· Store in original containers.
· Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records
• fosinopril sodium: CAS:88889-14-9

PERSONAL PROTECTION




RESPIRATOR

Particulate
Consult your EHS staff for recommendations

EYE

■ When handling very small quantities of the material eye protection may not be required.
For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
· Chemical goggles
· Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
· Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.
Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
· frequency and duration of contact,
· chemical resistance of glove material,
· glove thickness and
· dexterity
Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
· Contaminated gloves should be replaced.
Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
· Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
· Double gloving should be considered.
· PVC gloves.
· Protective shoe covers.
· Head covering.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.
· polychloroprene
· nitrile rubber
· butyl rubber
· fluorocaoutchouc
· polyvinyl chloride
Gloves should be examined for wear and/ or degradation constantly.

OTHER

· For quantities up to 500 grams a laboratory coat may be suitable.
· For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
· For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
· For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
· Eye wash unit.
· Ensure there is ready access to an emergency shower.
· For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.
Mixes with water.

State	Divided solid	Molecular Weight	585.65
Melting Range (°F)	Not available	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	Not available.	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	>2.8x10(-8)
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE
Crystalline solid; mixes with water, alcohol, chloroform, methylene chloride.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY
· Presence of incompatible materials.
· Product is considered stable.

STORAGE INCOMPATIBILITY
■ Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

FOSINOPRIL SODIUM

TOXICITY AND IRRITATION
FOSINOPRIL SODIUM:
■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (mouse) LD50: 3000 mg/kg*	Eye: SEVERE *

■ The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
Skin: non-irritating *
* Bristol-Myers squibb

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions
All waste must be handled in accordance with local, state and federal regulations.
¦ Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.
A Hierarchy of Controls seems to be common - the user should investigate:
· Reduction
· Reuse
· Recycling
· Disposal (if all else fails)
This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.
· Recycle wherever possible.
· Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

No data for fosinopril sodium (CAS: , 88889-14-9)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

■ Ingestion may produce health damage*.
■ Cumulative effects may result following exposure*.
■ Possible respiratory sensitiser*.
■ May possibly be harmful to the foetus/ embryo*.
* (limited evidence).

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■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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