Enalapril Maleate

sc-205666

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Enalapril Maleate

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

NFPA

SUPPLIER
Company: Santa Cruz Biotechnology, Inc.
Address:
2145 Delaware Ave
Santa Cruz, CA 95060
Telephone: 800.457.3801 or 831.457.3800
Emergency Tel: CHEMWATCH: From within the US and Canada: 877-715-9305
Emergency Tel: From outside the US and Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

PRODUCT USE
Antihypertensive. Inhibitor of the enzyme involved in the conversion of angiotensin I to angiotensin II. Also used in the treatment of congestive heart failure. Normally given by mouth. Enalapril owes its activity to enalaprilat (the diacid) to which it is converted after oral administration. Haemodynamic effects are seen within an hour of a single oral dose and a maximum effect occurs after 4-6 hours.

SYNONYMS
C20-H28-N2-O5.C4-H4-O4, "L-proline, 1-[N-(1-ethoxycarbonyl)-3-phenylpropyl)-L-alanyl]-(S)-, ", "L-proline, 1-[N-(1-ethoxycarbonyl)-3-phenylpropyl)-L-alanyl]-(S)-, ", "(Z)-2-butenedioate (1:1)", "(Z)-2-butenedioate (1:1)", "N-[(S)-1-ethoxycarbonyl)-3-phenylpropyl)-L-alanyl-L-proline maleate", (1:1), "N-[(S)-1-ethoxycarbonyl)-3-phenylpropyl)-L-alanyl-L-proline maleate", (1:1), (S)-1-(N-(1-ethoxycarbonyl)-3-phenylpropyl)-L-alanyl]-L-proline, maleate, (S)-1-(N-(1-ethoxycarbonyl)-3-phenylpropyl)-L-alanyl]-L-proline, maleate, "angiotensin converting enzyme (ACE) inhibitor", antihypertensive, Vasotec, Renitec, Innovace, MK-0421, "MK 421", "MK 421 maleate", "L-154, 739", "L-154, 739", SP2111, Alphapril

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW
RISK
Harmful if swallowed.
Irritating to eyes, respiratory system and skin.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage 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. Side effects of treatment include itch, rash, taste disturbance, allergy, loss of white blood cells, stomach upset, low blood pressure, increased heart rate, mouth ulcers, "pins and needles" in the hands, cough, wheeze and swollen lymph nodes. Damage to the kidneys and low blood pressure may be severe. Large areas of swelling may occur in the tongue, lips, face, extremities, and throat, which may be life-threatening. An itchy skin rash with redness and blistering may occur. Symptoms of low blood pressure are more likely in people who have been on low salt diets and prolonged treatment with diuretics. ACE inhibitors can cause reduction in urine output, and rarely, death due to kidney failure.

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. There may be damage to the cornea. Unless treatment is prompt and adequate there may be permanent loss of vision. Conjunctivitis can occur following repeated exposure.

SKIN

■ This material can cause inflammation of the skin oncontact in some persons.
■ The material may accentuate any pre-existing dermatitis condition.
■ 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 can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
■ 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

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.
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 human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the 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. Prime symptom is breathlessness; lung shadows show on X-ray.
Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).
ACE inhibitors may aggravate kidney and collagen vascular disorders. They may cause injury and death to the fetus late in pregnancy. There has been low blood pressure of the newborn, kidney failure, underdevelopment of the skull and lungs, insufficient amniotic fluid, and fetal growth retardation and limb contractures. Miscarriage or stillbirth may occur. ACE inhibitors can cause growths in glands, but rarely cause malignant cancer.
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. An individual may be predisposed to such anti-body mediated reaction if other chemical agents have caused prior sensitization (cross-sensitivity).
Kidney and liver effects were observed in repeat-dose oral toxicity studies, up to 1-year in duration, in dogs. The no-observed-adverse-effect level (NOEL) was 15 mg/kg/day.
No teratogenic effects of oral enalapril were seen in studies of pregnant rats and rabbits. Doses were 330 times (in rats) and 50 times (in rabbits) the maximum recommended human dose.
There was no evidence of a tumourigenic effect when enalapril was administered for 106 weeks at doses up to 90 mg/kg/day (150 times the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively (150 and 300 times the maximum daily human dose) and shows no evidence of carcinogenicity. Neither enalapril maleate or its active diacid are mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxic assays: rec-assay, reverse mutation assay with E.coli, sister chromatid exchange with cultured mammalian cells and the micronucleus test with mice, as well as in an in vivo cytogenic study using mouse bone marrow.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	3		

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

NAME	CAS RN	%
enalapril maleate	76095-16-4	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

■

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:
- For advice, contact a Poisons Information Center or a doctor.
- Urgent hospital treatment is likely to be needed.
- If conscious, give water to drink.
- INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

NOTE: Wear a protective glove when inducing vomiting by mechanical means.

- In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.
- If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the MSDS should be provided. Further action will be the responsibility of the medical specialist.
- If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS.

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.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

■ If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

■

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor, without delay.

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. If patients are well after 6 hours, they are considered medically fit for discharge. Oral activated charcoal may be given to patients who have ingested a large overdose if they present within a few hours. There is unlikely to be a significant benefit from repeated doses of activated charcoal. Hemodialysis may increase the clearance of some drug but there is no indication for the procedure. While angiotensin II is a logical antidote for overdose, it is not generally available and should not be required.Hypotension should be treated with IV fluids (normal saline) and positioning of the patient. A central line may be useful to monitor fluid replacement in patients with heart failure or severe renal impairment. Small doses of vaso-constrictors (e.g. adrenalin) may be given if the patient fails to respond. Most ACE inhibitors (except captopril and lisinopril) are given as pro-drugs which have little activity. These pro-drugs have good bioavailability and are generally well absorbed. They are rapidly metabolized by esterases to active metabolites (generally the diacids). Captopril and lisinopril are not as well absorbed and have lower bioavailability than the pro-drugs.Naming convention adds the extension "prilat" to the common name of the pro-drug.

BIOAVAILABILITY:

Drug	Time to Peak (hrs)	Bioavailability %	Urinary excretion of active moiety (normal renal function)	Approx. half-life (hrs)!
Alacepril *				
Altiopril *				
Benazepril*				
Captopril	0.7-1.3	65	>70	3.5-32**
Cilazapril*				
Delapril *		50		1.2-12.9**
Enalapril *		>50		8-36**
Fosinopril*				
Lisinopril			88	6-19.5**
Moexipril				
Pentopril *		60-70		2.7-10.5**
Perindopril*				5.0-31 **
Quinapril *			>50	5.0-31**
Ramipril *			20-40	8.0-16.0**
Spirapril *				
Trandopril*				
Zofenopril*				

* Given as the pro-drug; activity is due to metabolites (-prilat)
** Higher figure for patients with renal failure
! Most ACE inhibitors have biphasic kinetics; figures are for apparent half-lives
HyperTox 3.0 http://www.newcastle.edu.au/department/md/htas/ACE00001.HTML
When involvement of the tongue, glottis or larynx is likely to cause airway obstruction, appropriate therapy (e.g. adrenalin) should be promptly administered. Medical therapy of progressive edema should be aggressive. Failing a rapid response, mechanical methods to secure an airway should be undertaken before massive edema complicates oral or nasal intubation or surgical procedures. (e.g. cricothyroidotomy or tracheostomy). Patients responding to medical treatment should be observed carefully for a possible rebound phenomenon. Monitoring of white blood cell counts, especially in patients with collagen vascular disease and/or renal disease is advisable during ACE therapy due to the appearance of agranulocytosis and bone-marrow depression in some patients. Australian Prescriptions Product Guide.
About 55-75% of enalapril is rapidly absorbed from the gastrointestinal tract following oral administration, and is extensively hydrolysed to its active form, enalaprilat. Both are excreted mainly in the urine and also in the faeces. Enalaprilat is removed by haemodialysis.
Hypotension may be treated by intravenous infusion of normal saline solution.
Mercke, Sharp and Dohme.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA

■
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

FIRE FIGHTING

■
- Alert Emergency Responders and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

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.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO_2), nitrogen oxides (NOx), sulfur oxides (SOx), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.
May emit corrosive fumes.

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

■
- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact by using protective equipment.
- Use dry clean up procedures and avoid generating dust.
- Place in a suitable, labelled container for waste disposal.

MAJOR SPILLS
■ Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- Recover product wherever possible.
- IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise emergency services.

ACUTE EXPOSURE GUIDELINE LEVELS (AEGL) (in ppm)

AEGL 1: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.
AEGL 2: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.
AEGL 3: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

■
- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately.
- Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

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

■
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

■
- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS

+	X	+	X	X	+

X: Must not be stored together
O: May be stored together with specific preventions
+: May be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

• enalapril maleate: CAS:76095-16-4

MATERIAL DATA

ENALAPRIL MALEATE:

■ It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

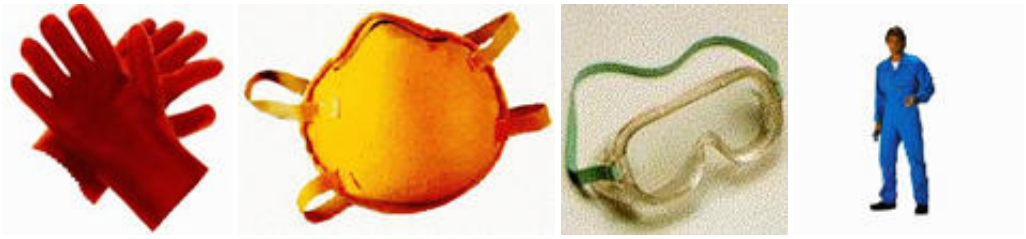
OSHA (USA) concluded that exposure to sensory irritants can:

- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

CEL TWA: 0.1 mg/m3 (Mercke, Sharp and Dohme)

The recommended daily therapeutic dose of enalapril is 10-40 mg. The clinical response curve is relatively flat, with increasing dose resulting in a lengthening of the effect (reduction of blood pressure) rather than heightening it. In normotensive individuals, 1 mg is considered ineffective in reducing blood pressure and is considered a no-observable-effect level (NOEL). Therefore in order that 1 mg is not exceeded in an 8-hour day, an exposure limit of 0.1 mg/m3 is recommended.

PERSONAL PROTECTION



Consult your EHS staff for recommendations

EYE

■

- Safety glasses with side shields.
- Chemical goggles.
- Contact lenses pose a special hazard; soft lenses may absorb irritants and all lenses concentrate them. DO NOT wear contact lenses.

HANDS/FEET

■ 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.

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

■
- Overalls.
- P.V.C. apron.
- Barrier cream.
- Skin cleansing cream.
- Eye wash unit.

■
- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory . These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

RESPIRATOR

■

Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
10 x PEL	P1	-	PAPR-P1
	Air-line*	-	-
50 x PEL	Air-line**	P2	PAPR-P2
100 x PEL	-	P3	-
		Air-line*	-
100+ x PEL	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow
Explanation of Respirator Codes:
Class 1 low to medium absorption capacity filters.
Class 2 medium absorption capacity filters.
Class 3 high absorption capacity filters.
PAPR Powered Air Purifying Respirator (positive pressure) cartridge.
Type A for use against certain organic gases and vapors.
Type AX for use against low boiling point organic compounds (less than 65ºC).
Type B for use against certain inorganic gases and other acid gases and vapors.
Type E for use against sulfur dioxide and other acid gases and vapors.
Type K for use against ammonia and organic ammonia derivatives
Class P1 intended for use against mechanically generated particulates of sizes most commonly encountered in industry, e.g. asbestos, silica.
Class P2 intended for use against both mechanically and thermally generated particulates, e.g. metal fume.
Class P3 intended for use against all particulates containing highly toxic materials, e.g. beryllium.
The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.
Use appropriate NIOSH-certified respirator based on informed professional judgement. In conditions where no reasonable estimate of exposure can be made, assume the exposure is in a concentration IDLH and use NIOSH-certified full face pressure demand SCBA with a minimum service life of 30 minutes, or a combination full facepiece pressure demand SAR with auxiliary self-contained air supply. Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

ENGINEERING CONTROLS

■
- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
- Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.
- If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. Such protection might consist of:

(a): particle dust respirators, if necessary, combined with an absorption cartridge;
(b): filter respirators with absorption cartridge or canister of the right type;
(c): fresh-air hoods or masks

- Build-up of electrostatic charge on the dust particle, may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to efficiently remove the contaminant.

Type of Contaminant:	Air Speed:
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favorable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity

generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.
Does not mix with water.

State	Divided solid	Molecular Weight	492.58
Melting Range (°F)	289.4- 291.2	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	2.4-2.8
Decomposition Temp (°F)	176 (3 weeks)	pH (as supplied)	Not applicable
Autoignition Temp (°F)	809.6	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

White to off-white, free flowing crystalline powder; mixes with water (0.25 gm/100 ml). Slightly photosensitive.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

■

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerization will not occur.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.

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

Section 11 - TOXICOLOGICAL INFORMATION

enalapril maleate

TOXICITY AND IRRITATION

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (rat) LD50: 2973 mg/kg	Eye: SEVERE *
Oral (rat) LD50: 2000 mg/kg *	Skin (intact): non-irritating*
Subcutaneous (rat) LD50: 1418 mg/kg	Skin (abraded): slight *
Intravenous (rat) LD50: 849 mg/kg	
Oral (mouse) LD50: 3507 mg/kg	
Oral (mouse) LD50: 2000 mg/kg *	
Subcutaneous (mouse) LD50: 1160 mg/kg	
Intravenous (mouse) LD50: 859 mg/kg	
Intravenous (mouse) LD50: 750 mg/kg *	
Oral (dog) LDLo: 200 mg/kg *	

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.
The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Hepatocellular necrosis, dermatitis after systemic exposure, acute pulmonary oedema, dyspnea, cyanosis, renal function tests depressed, changes in urine composition, olfaction effects, convulsions, ataxia, respiratory depression, changes in urine composition, leucopenia, normocytic anaemia, reproductive system tumours, specific developmental abnormalities (urogenital system, craniofacial including nose and tongue, musculoskeletal system), foetoxicity, maternal effects, effects on newborn, foetolethality recorded.
* Mercke, Sharp and Dohme

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:
ENALAPRIL MALEATE:
■ DO NOT discharge into sewer or waterways.
Enalapril maleate does not exhibit environmentally significant acute toxic effects to Pimephales promelas (Fathead minnow) and Daphnia magna (water flea).
Fish LC50 (96 h): Fathead minnow 364 mg/l
Daphnia magna LC50 (48 h): >1000 mg/l
Activated Sludge Respiration Inhibition Test (ASPRIT) results indicate that concentrations below 1000 mg/l are not expected to upset an acclimated activated sludge treatment system.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions
All waste must be handled in accordance with local, state and federal regulations.
¦ Puncture containers to prevent re-use and bury at an authorized landfill.
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.
- Dispose of by: Burial in a licensed land-fill or Incineration in a licensed apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

enalapril maleate (CAS: 76095-16-4) is found on the following regulatory lists;
"Canada Domestic Substances List (DSL)"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE
■ Cumulative effects may result following exposure*.
■ May be harmful to the fetus/ embryo*.
* (limited evidence).

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

■ Classification of the mixture 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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