Dorzolamide Hydrochloride

sc-207596

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Dorzolamide Hydrochloride

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
Anti-glaucoma agent. A potent inhibitor of carbonic anhydrase II with a relatively long duration of action. An ocular instillation of a 2% solution in monkeys, twice daily, resulted in a significant reduction of intraocular pressure 16 hours post-dose.

SYNONYMS
C10-H16-N2-O4-S3.HCl, "4H-thieno(2, 3-b)thiopyran-2-sulfonamide, 5, 6-dihydro-4-(ethylamino)-6-", "methyl-, 7, 7-dioxide, monohydrochloride, (4S-trans)-", "4H-thieno(2, 3-b)thiopyran-2-sulfonamide, 5, 6-dihydro-4-(ethylamino)-6-", "methyl-, 7, 7-dioxide, monohydrochloride, (4S-trans)-", MK-0507, Trusopt, "anti-glaucoma agent", "carbonic anhydrase inhibitor/ CAI"

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW
RISK
Harmful if swallowed.

POTENTIAL HEALTH EFFECTS

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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.
■ Considered an unlikely route of entry in commercial/industrial environments.
■ Side effects of diuretics include stomach upset (loss of appetite, nausea and vomiting), loss of weight, mineral disturbances, constipation, frequent urination, spasmodic pains in the kidney, kidney stones, crystals in the urine, skin eruptions, itchiness, loss of white blood cells and platelets, headache, weakness, nervousness, difficulty swallowing, sedation, tiredness, depression, confusion, disorientation, dizziness, inco-ordination, tremor, ringing in the ears and tingling, numbness and "pins and needles" in the hands, feet and face. Anemia, hepatitis with bile flow obstruction, rash, jaundice and loss of red blood cells may occur.
■ Agranulocytosis is an acute condition with loss of white blood cells, especially those with multiple nuclei. This may lead to infected ulcers in the throat, intestine, other mucous membranes and skin.

EYE

■ Although the material is not thought to be an irritant, direct contact with the eye may produce transient discomfort characterized by tearing or conjunctival redness (as with windburn).
■ Allergic reactions of the conjunctiva (blepharoconjunctivitis) are often a result of interaction of the allergen with antibodies of the IgE class.

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.
■ Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's edema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitization potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitizing substance which is widely distributed can be a more important allergen than one with stronger sensitizing potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

INHALED

■ The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified using animal models). Nevertheless, 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

■ Principal routes of exposure are usually by skin contact/absorption and inhalation of generated dust.
When applied topically dorzolamide reaches the systemic circulation where it binds selectively to carbonic anhydrase isoenzyme II in red blood cells and accumulates during chronic dosing. This is also true for its N-desethyl metabolite which is more selectively bound on carbonic anhydrase I. Chronic use of the 2% ocular solution may produce conjunctivitis and lid reactions.
In a two-year study of dorzolamide hydrochloride administered orally to male and female Sprague-Dawley rats, urinary bladder papillomas were seen in male rats in the highest dosage group of 20 mg/kg/day) (250 times the recommended human opthalmic dose), Papillomas were not seen in rats given oral doses given oral doses equivalent to approximately twelve times the recommended human opthalmic dose. No treatment related tumours were seen in a 21-month study in female and male mice given oral doses up to 75 mg/kg/day (approximately 900 times the recommended human opthalmic dose). the increased incidence of urinary papillomas seen in high dose male rats is a class-effect of carbonic anhydrase inhibitors in rats. Rats are particularly prone to developing papillomas in response to foreign bodies, particularly compounds causing crystalluria and diverse sodium salts. No changes in bladder urothelium were seen in dogs given oral dorzolamide for one year at 2 mg/kg/day (25 times the opthalmic dose) or monkeys dosed topically to the eye at 0.4 mg/kg/day (approximately 5 times the recommended human opthalmic dose) for one year.
The following tests for mutagenic potential were negative: in vivo (mouse) in the cytogenic assay; in vitro in the chromosomal aberration assay; in

the alkaline elution assay; in the V-79 assay; in the Ames test.
In reproduction studies of dorzolamide hydrochloride in rats, there was no adverse effect on the reproductive capacity of males and females at doses up to 188 or 94 times, respectively, the recommended human opthalmic dose. Developmental toxicity studies with dorzolamide hydrochloride in rats at oral doses equal to or greater than 2.5 mg/kg/day (31 times the recommended human opthalmic dose) revealed malformations of the vertebral bodies. These malformations occurred at doses that caused metabolic acidosis with decreased body weight gain in dams and decreased foetal weights. No treatment related malformations were seen at 1 mg/kg/day (13 times the recommended human opthalmic dose). There was no treatment-related foetal malformations in developmental studies with dorzolamide hydrochloride in rats at oral doses up to 10 mg/kg/day (125 times the recommended human opthalmic dose). There are no adequate and well controlled studies in pregnant women.
In a study of dorzolamide hydrochloride in lactating rats, decreases in body weight gain of 5-7% in offspring at an oral dose of 7.5 mg/kg/day (94 times the recommended human opthalmic dose) were seen during lactation. A slight delay in postnatal development (incisor eruption, vaginal canalisation and eye openings), secondary to lower foetal body weight were noted.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	0		
Reactivity:	0		
Chronic:	2		

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

NAME	CAS RN	%
dorzolamide hydrochloride	130693-82-2	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

■ If poisoning occurs, contact a doctor or Poisons Information Center.
- 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.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

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.

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

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 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
■ Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available
Relative Vapor Density (air=1):	>1

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

FIRE FIGHTING
■
- 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
■
- Solid which exhibits difficult combustion or is difficult to ignite.
- 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), nitrogen oxides (NOx), sulfur oxides (SOx) and hydrogen chloride.

FIRE INCOMPATIBILITY
■ Avoid contamination with strong oxidizing agents as ignition may result.

PERSONAL PROTECTION
Glasses:
Chemical goggles.
Gloves:
Respirator:
Particulate

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Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Wear impervious gloves and safety glasses.
- Use dry clean up procedures and avoid generating dust.
- Sweep up or vacuum up (consider explosion-proof machines designed to be grounded during storage and use).
- Place spilled material in clean, dry, sealable, labeled container.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Emergency Responders and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Stop leak if safe to do so.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labeled containers for recycling.
- Neutralize/decontaminate residue.
- Collect solid residues and seal in labeled drums for disposal.
- Wash area and prevent runoff into drains.
- After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.
- 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

- Limit all unnecessary personal contact.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- When handling DO NOT eat, drink or smoke.
- Always wash hands with soap and water after handling.
- Avoid physical damage to containers.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.

RECOMMENDED STORAGE METHODS

- Polyethylene or polypropylene container.
- Packing as recommended by manufacturer
- Check all containers are clearly labeled and free from leaks.

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STORAGE REQUIREMENTS

■

- Keep dry.
- Store in original containers.
- Keep containers securely sealed.
- No smoking, naked lights or ignition sources.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials.
- Protect containers against physical damage.
- 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

• dorzolamide hydrochloride: CAS:130693-82-2

MATERIAL DATA

DORZOLAMIDE HYDROCHLORIDE:
CEL TWA: 0.04 mg/m3 (Mercke, Sharp and Dohme)
Repeat dose studies show a number of histologic changes, including urothelial hyperplasia of the urinary bladder and appearance of cytoplasmic granules in renal papillary epithelium in mice, and retention of the primary spongiosa (in bone) and minor decreases in erythroid parameters in dogs and monkeys. The lowest no-effect levels for these changes, most of which are considered to be secondary to the pharmacological action of dorzolamide, was 0.05 mg/kg/day (2.5 mg for a 50 kg person). Developmental toxicity, consistent with this class of compound, was seen in the presence of maternal toxicity in rabbits with a no-effect level of 1 mg/kg/day. Terminal half-life of dorzolamide in red blood cells is approximately 4 months. At a steady state, inhibition of carbonic anhydrase in red blood cells has been below that anticipated to be necessary for pharmacologic effects on renal and respiratory function. An acceptable daily intake (ADI) of 0.4 mg/day is thought to provide a 10-fold safety factor with respect to the clinical dose (4 mg) applied as a 2% opthalmic solution. This ADI was used to derive the recommended exposure limit of 0.04 mg/m3 (as an 8-hour time weighted average) and a wipe test criteria of 0.4 mg/100cm2.

■ Airborne particulate or vapor must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

PERSONAL PROTECTION

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Consult your EHS staff for recommendations
■ EYE
No special equipment needed when handling small quantities of substance.
For bulk handling wear:
Chemical goggles or
Face shield.

HANDS/FEET

Rubber gloves
PVC gloves
Protective shoe covers
Head covering.

OTHER

No special equipment when handling small quantities of substance otherwise:
Coveralls
For Emergencies:
Vinyl suit
Safety shower

RESPIRATOR

High Efficiency Dust Respirator (P2, P3)
For non-routine emergencies wear full face mask self-contained breathing apparatus.

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

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

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HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.
Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.
The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.
Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapors, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, 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.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable 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 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 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.
Mixes with water.

State	Divided solid	Molecular Weight	360.9
Melting Range (°F)	527	Boiling Range (°F)	Not available
Solubility in water (g/L)	Miscible	Flash Point (°F)	Not available
pH (1% solution)	5.65 (2% sol)	Decomposition Temp (°F)	Not available.
pH (as supplied)	Not applicable	Autoignition Temp (°F)	Not available
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

Solid; mixes with water.

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

dorzolamide hydrochloride

TOXICITY AND IRRITATION

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

TOXICITY	IRRITATION
Oral (rat) LD50: 1927 mg/kg	Nil Reported
Subcutaneous (rat) LD50: >2000 mg/kg	
Intravenous (rat) LD50: 726 mg/kg	
Oral (mouse) LD50: 1320 mg/kg	
Subcutaneous (mouse) LD50: >2000 mg/kg	
Intravenous (mouse) LD50: 469 mg/kg	
Oral (dog) LD50: >250 mg/kg	
ADI: 0.4 mg/day *	

* Mercke, Sharp and Dohme

Ptosis, somnolence, ataxia, dermatitis after systemic exposure, tremor, dyspnea, increased urine volume, inflammation/ necrosis/ scarring of bladder, weight loss/ decreased weight gain, foetotoxicity, specific developmental abnormalities (musculoskeletal system), maternal effects, effects on newborn, foetotoxicity recorded.

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:
DORZOLAMIDE HYDROCHLORIDE:
Ecotoxicology:
Dorzolamide does not exhibit environmentally significant acute toxic effects towards Daphnia magna (water flea) and Pimephales promelas (fathead minnow). Based on the activated sludge respiration inhibition test (ASRIT) EC50 results, concentrations less than 800 mg/l are not expected to upset an unacclimated activated sludge system in a waste-water treatment plant.
Fish LC50 (96 h): fathead minnow >1000 mg/l
Daphnia magna LC50 (48 h): 699 mg/l
Environmental fate:
Test indicate that dorzolamide is not readily biodegradable by an unacclimated activated sludge culture. After 28 days, approximately 20% of the substance was biotransformed into two less polar metabolites. The substance is not readily hydrolysed as evidenced in a 28 day respirometry study and no biological inhibition was seen at concentrations less than or equal to 400 mg/l

Section 13 - DISPOSAL CONSIDERATIONS

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Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

- Consult manufacturer for recycling options and recycle where possible .
- Consult Waste Management Authority for disposal.
- Incinerate residue at an approved site.
- Recycle containers where possible, or dispose of in an authorized landfill.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

No data for dorzolamide hydrochloride (CAS: , 130693-82-2)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

■ Possible skin sensitizer*.
* (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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