Oxybutynin Chloride

sc-208141

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Oxybutynin Chloride

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

NFPA


SUPPLIER
Santa Cruz Biotechnology, Inc.
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Santa Cruz, California 95060
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EMERGENCY:
ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS
C22-H31-N-O3.HCl, C6H4(C(OH)(C6H11)CO2CH2CCH2N(C2H5)2.HCl, "cyclohexaneglycolic acid, alpha-phenyl-, 4-(diethylamino)-2-butynyl ester, ", hydrochloride, "alpha-cyclohexyl-alpha-hydroxybenzeneacetic acid 4-(diethylamino)-2-", "butynyl ester hydrochloride", "alpha-phenylcyclohexaneglycolic acid 4-(diethylamino) 2-butynyl ester", hydrochloride, "4-diethylamino-2-butynyl phenylcyclohexylglycolic acid hydrochloride", "oxibutina hydrochloride", "oxybutynin chloride", Ditropan, Dridase, "Lyrinel XL", Pollakisu, Tropax, "anticholinergic/ antimuscurinic/ antihistamine", oxytrol

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

Harmful if swallowed.

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.

■ Antihistamines have side effects such as sedation, stomach upset (nausea, vomiting, diarrhea or constipation), blurred vision, ringing in the ears, mood changes, irritability, nightmares, loss of appetite, difficulty urinating, dry mouth, chest tightness and tingling, heaviness and weakness in the hands, nervousness, restlessness, irritability, feeling of well-being, disturbed eye movements, difficulties moving the face, "pins and needles", palpitations, faintness, increased heart rate, uncommonly irregular heart rhythms, lung swelling, and disturbed sleep and dreaming. Treatment may cause side effects within 15 minutes including a dry mouth and throat, blocked nose, wheeze, thick phlegm, fever, sweating, smell disturbances, skin flushing, double vision and dilated pupils.

■ Antimuscarinic agents (muscarinic antagonists) operate on the muscarinic acetylcholine receptors. The majority of anticholinergic drugs are antimuscarinics. Side-effects normally associated with antimuscarinic agents are generally reduced because of preferred binding to gastric mucosa receptors.

The most common adverse events reported by patients receiving antimuscarinics are dry mouth, headache, constipation, vertigo/dizziness, and abdominal pain. Dry mouth, constipation, abnormal vision (accommodation abnormalities), urinary retention, and xerophthalmia are expected side effects of antimuscarinic agents.

When a significant amount of an anticholinergic is taken into the body, a toxic reaction known as acute anticholinergic syndrome may result. This may happen accidentally or intentionally as a consequence of recreational drug use. Anticholinergic drugs are usually considered the least enjoyable by experienced recreational drug users, possibly due to the lack of euphoria caused by them. The risk of addiction is low in the anticholinergic class. The effects are usually more pronounced in the elderly, due to natural reduction of acetylcholine production associated with age.

Possible effects of anticholinergics include:

· Ataxia; loss of coordination; decreased mucus production in the nose and throat; consequent dry, sore throat;xerostomia or dry mouth with possible acceleration of caries; cessation of perspiration; consequent decreased epidermal thermal dissipation leading to warm, blotchy, or red skin; increased body temperature; pupil dilation (mydriasis); consequent sensitivity to bright light (photophobia); loss of accommodation (loss of focusing ability, blurred vision - cycloplegia); double vision (diplopia); increased heart rate (tachycardia); easily startled; urinary retention; diminished bowel movement, sometimes ileus; increased intraocular pressure, dangerous for people with narrow-angle glaucoma; shaking

Possible effects in the central nervous system resemble those associated with delirium, and may include:

· Confusion; disorientation; agitation; euphoria or dysphoria; respiratory depression; memory problems; inability to concentrate; wandering thoughts; inability to sustain a train of thought; incoherent speech; wakeful myoclonic jerking; unusual sensitivity to sudden sounds; illogical thinking; photophobia; visual disturbances; periodic flashes of light; periodic changes in visual field; visual snow; restricted or "tunnel vision" ; visual, auditory, or other sensory hallucinations; warping or waving of surfaces and edges; textured surfaces; "dancing" lines; "spiders", insects; lifelike objects indistinguishable from reality; hallucinated presence of people not actually there; rarely: seizures, coma and death

Acute anticholinergic syndrome is completely reversible and subsides once all of the toxin has been excreted. Ordinarily, no specific treatment is indicated. However, in extreme cases, especially those that involves severe distortions of mental state, a reversible cholinergic agent such as physostigmine may be used..

Muscarine-like drugs activate muscarinic receptors (one type of cholinergic receptor), affecting both peripheral and central nervous systems. Molecular biology techniques have identified at least 5 different muscarinic receptors. At present the significance of M4 and M5 is unclear.

EYE

■ There is some evidence to suggest that this material can causeeye irritation and damage in some persons.

■ Anticholinergic eye drops can cause stinging, dryness, redness, itch, dilated pupils, and loss of focus with blurred vision. Pupil Reflexes may be lost or diminished for 3 days.

SKIN

■ The material is not thought to be a skin irritant (as classified using animal models). Abrasive damage however, may result from prolonged exposures.

■ Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.

■ 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.

■ The use of anticholinergic agents is associated with temporary impairment of vision. Anticholinergic agents produce peripheral antimuscarinic effects including an increase in heart rate, decreased production of saliva, sweat, and bronchial, nasal, gastric and intestinal secretions, decreased intestinal motility and inhibition of urination. Side effects associated with the use of anticholinergics include dryness of the mouth, with difficulty in swallowing and talking, thirst, dilation of the pupils (mydriasis), loss of accommodation (cycloplegia), and photophobia, flushing and dryness of the skin, transient bradycardia, followed by tachycardia with palpitations and arrhythmias, urinary urgency

and difficulty of retention, and a reduction in tone and motility of the gastro-intestinal tract. Vomiting, giddiness and staggering and restrosternal pain may occur on occasion. Toxic doses may produce tachycardia, rapid respiration, hyperpyrexia and central nervous system stimulation characterised by restlessness, confusion, excitement, paranoid and psychotic reactions, hallucinations, delirium and occasionally, seizures and convulsions. A rash may be visible on the upper trunk or face. Central effects generally involve the stimulation of the medulla and higher cerebral centres which manifests themselves as a mild central vagal excitation, respiratory stimulation and depression of central motor mechanisms, particularly those associated with the extrapyramidal tract. Severe intoxication may produce central nervous system depression with ataxia, drowsiness, stupor, unconsciousness, coma, circulatory and respiratory system arrest, and death.
■ 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 limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.
Prolonged exposure to anticholinergic agents may irritate the eyes, causing allergic lid reactions, conjunctivitis, swelling, excess blood flow to the eyes, and sensitivity to light. Increase in eye pressure may lead to closed angle glaucoma.
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.
Wide area external application of antihistamines can cause various side effects, including sensitization and eczema.
Long-term use of antihistamines can cause sugar in the urine, obstructive jaundice, skin discoloration associated with loss of platelets, early periods, loss of milk production, breast development in males and decreased sex drive. Disturbances in the blood include anemia, loss of white blood cells and platelets.
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.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
oxybutynin hydrochloride	1508-65-2	>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:

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 fumes or combustion products are inhaled remove from contaminated area. · Other measures are usually unnecessary.

NOTES TO PHYSICIAN

■ Treatment regime for atropine intoxication:Empty the stomach by aspiration and lavage. The use of charcoal to prevent absorption, followed by lavage has been suggested.<\div>.

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.

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 (CO_2), hydrogen chloride, phosgene, nitrogen oxides (NOx), 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
· 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.
· Polyethylene or polypropylene container.
· Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

■ Observe manufacturer's storing and handling recommendations.
NOTE: Store in the dark.

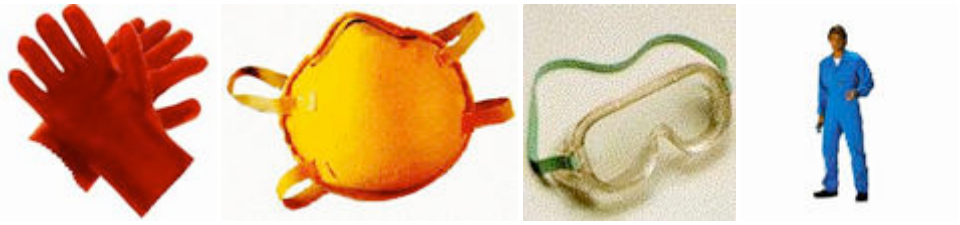
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

• oxybutynin hydrochloride: CAS:1508-65-2

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

■ For potent pharmacological agents:
Powders
To prevent contamination and overexposure, no open handling of powder should be allowed.
· Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
· In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
· Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
· An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).
· Powder should be put into solution or a closed or covered container after handling.
· If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
Solutions Handling:
· Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolisation. If the procedures have a potential for aerosolisation, an air-purifying respirator is to be worn by all personnel in the immediate area.
· Solutions used for procedures where aerosolisation may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation.
· In situations where this is not feasible (may include animal dosing), an air-purifying respirator is to be worn by all personnel in the immediate area. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
· Ensure gloves are protective against solvents in use.
Unless written procedures, specific to the workplace are available, the following is intended as a guide:

· For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets *; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*,
· 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.
Does not mix with water.

State	Divided solid	Molecular Weight	394.0
Melting Range (°F)	264.2- 266	Viscosity	Not Applicable
Boiling Range (°F)	Not applicable	Solubility in water (g/L)	Partly 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)	Negligible
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 available

APPEARANCE

White crystalline solid; does not mix well with water. Oxybutynin contains one stereocenter. Commercial formulations are sold as the racemate. The (R)-enantiomer is a more potent anticholinergic than either the racemate or the (S)-enantiomer, which is essentially without anticholinergic activity at the doses used in clinical practice. However, (R)-oxybutynin administered alone offers little or no clinical benefit above and beyond the racemic mixture. The other actions (calcium antagonism, local anesthesia) of oxybutynin are not stereospecific. (S)-Oxybutynin has not been clinically tested for its spasmolytic effects, but may be clinically useful for the same indications as the racemate, without the unpleasant anticholinergic side effects.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

· Presence of incompatible materials.
· Product is considered stable.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.
Heat and light accelerate decomposition.

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

Section 11 - TOXICOLOGICAL INFORMATION

OXYBUTYNIN HYDROCHLORIDE

TOXICITY AND IRRITATION

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

TOXICITY	IRRITATION
Oral (woman) TDLo: 2 mg/kg	Eye (rabbit): 1%
Oral (rat) LD50: 460 mg/kg	
Intraperitoneal (rat) LD50: 223 mg/kg	
Subcutaneous (rat) LD50: 740 mg/kg	
Intravenous (rat) LD50: 61 mg/kg	
Oral (mouse) LD50: 725 mg/kg	
Intraperitoneal (mouse) LD50: 185 mg/kg	
Subcutaneous (mouse) LD50: 2225 mg/kg	
Oral (dog) LD50: >400 mg/kg	

Mydriasis, parasympatholytic effects, adrenal cortex hyperplasia, changes in spleen, specific developmental effects (musculoskeletal system) effects on newborn recorded.
-
N-Desethyloxybutynin is an active metabolite of oxybutynin that is thought to be responsible for much of the adverse effects associated with the use of oxybutynin. N-Desethyloxybutynin plasma levels may reach as much as six times that of the parent drug after administration of the

immediate-release oral formulation. Alternative dosage forms have been developed in an effort to reduce blood levels of N-desethyloxybutynin and allow for a more steady concentration of oxybutynin to be achieved than is possible with the immediate release form. The long-acting formulations also allow once-daily administration instead of the twice-daily dosage required with the immediate-release form. The transdermal patch, in addition to the benefits of the extended-release oral formulations, bypasses the first-pass hepatic effect that the oral formulations are subject to

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.
¦ 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.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

No data for oxybutynin hydrochloride (CAS: , 1508-65-2)

Section 16 - OTHER INFORMATION

ND

Substance CAS Suggested codes oxybutynin hydrochloride 1508- 65- 2

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 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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