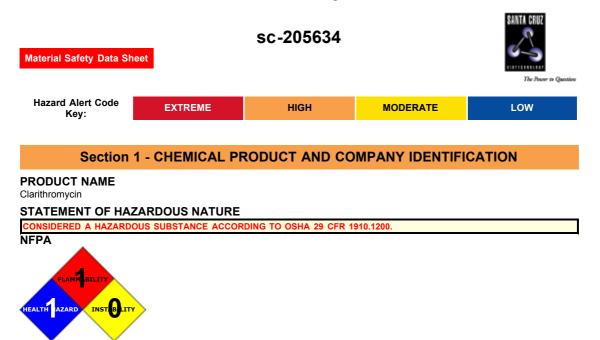
# Clarithromycin



### 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**

A macrolide antibiotic which acts by interfering with bacterial protein synthesis and is bacteriostatic or bactericidal depending on its concentration.

### SYNONYMS

C38-H69-N-O13, C38-H69-N-O13, "erythromycin, 6-O-methyl-", "erythromycin, 6-O-methyl-", clathromycin, 6-O-methylerythromycin, 6-O-methylerythromycin, 6-O-methylerythromycin A", "6-O-methylerythromycin A", Kalixocin, TE-031, "macrolide antibiotic"

### **Section 2 - HAZARDS IDENTIFICATION**

#### **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.

Sensitization of skin resulting in eruptions due to exposure to erythromycin has been reported. Higher concentrations may induce reversible deafness and liver damage, with upper abdominal pain, fever, liver enlargement and raised liver enzymes. EYE

• Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

SKIN

Skin contact is not thought to produce harmful health effects (as classified using animal models). Systemic harm, however,

has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions. 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.

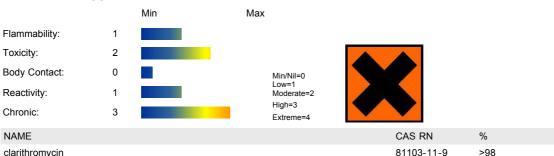
There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose

levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). 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 (nonthrombocytopenic purpura) may occur. An individual may be predisposed to such anti-body mediated reaction if other chemical agents have caused prior sensitization (cross-sensitivity).

Respiratory sensitization may result in allergic/asthma like responses; from coughing and minor breathing difficulties to bronchitis with wheezing, gasping.

### Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

#### **HAZARD RATINGS**



clarithromycin

### 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 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

for poisons (where specific treatment regime is absent):

BASIC TREATMENT

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 l/min.
- Monitor and treat, where necessary, for pulmonary edema .
- Monitor and treat, where necessary, for shock,
- Anticipate seizures
- DO NOT use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

#### ADVANCED TREATMENT

- · Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary edema.
- Hypotension with signs of hypovolemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L. EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994.

Treat	symp	tomat	ical	ly.
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#### Section 5 - FIRE FIGHTING MEASURES Vapour Pressure (mmHG): Nealiaible Upper Explosive Limit (%): Not available Specific Gravity (water=1): Not available Lower Explosive Limit (%): Not available

### **EXTINGUISHING MEDIA**

- ٠ 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 (CO2), 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

- 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. drv. 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: 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 • clarithromycin: CAS:81103-11-9

## MATERIAL DATA

### CLARITHROMYCIN:

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

CEL TWA: 3 mg/m3 (as erythromycin) (compare WEEL-TWA) A workplace environmental exposure standard (WEEL) is recommended by the AIHA and is based on reported clinical and industrial experience. The limit is thought to prevent possible alterations of the normal bacterial flora in the body or development of immunity to future therapeutic use.

#### 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

• 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.

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
- Eve 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	-

100+ x PEL

- 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 65°C).

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. Class P2 intended for use against all particulates containing highly toxic materials, 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. ٠
- 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.

Air Speed:
1-2.5 m/s (200-500 f/min.)
2.5-10 m/s (500-2000 f/min.)
Upper end of the range
1: Disturbing room air currents
2: Contaminants of high toxicity
3: High production, heavy use
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	747.96
Melting Range (°F)	Not available	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°F)	428	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

White to off-white crystalline powder; does not mix with water. Soluble in ethanol.

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

#### clarithromycin

#### TOXICITY AND IRRITATION

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

Oral (rat) LD50: 1270 mg/kg

Nil Reported

Intraperitoneal (rat) LD50: 669 mg/kg Subcutaneous (rat) LD50: >5000 mg/kg

Oral (mouse) LD50: 1230 mg/kg

Intraperitoneal (mouse) LD50: 850 mg/kg

Subcutaneous (mouse) LD50: >5000 mg/kg

Intravenous (mouse) LD50: 173 mg/kg

■ Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Change in motor activity, ptosis, somnolence, respiratory depression, corrosive after topical application, nausea, vomiting, gastrointestinal changes, changes in liver weight, change in blood or tissue levels transaminases, hepatitis, liver changes, changes in bladder weight, liver changes, normocytic anaemia, changes in serum composition, changes in kidney tubules, lachrymation, reproductive system tumours recorded.

### Section 12 - ECOLOGICAL INFORMATION

# Refer to data for ingredients, which follows: CLARITHROMYCIN:

DO NOT discharge into sewer or waterways.

### 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

#### clarithromycin (CAS: 81103-11-9) is found on the following regulatory lists;

"US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity", "US - California Proposition 65 - Reproductive Toxicity", "US - Maine Chemicals of High Concern List"

### **Section 16 - OTHER INFORMATION**

#### LIMITED EVIDENCE

Cumulative effects may result following exposure\*.

Possible respiratory and skin sensitizer\*.

May be harmful to the fetus/ embryo\*.
\* (limited evidence).

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 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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