

# GENERAL CURE CAPSULES

Chemwatch Material Safety Data Sheet  
Issue Date: 5-Jan-2006

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## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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### PRODUCT NAME

GENERAL CURE CAPSULES

### STATEMENT OF HAZARDOUS NATURE

**CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR  
1910.1200.**

### SUPPLIER

Company: Aquarium Pharmaceuticals Incorporated  
Address:  
PO Box 218  
Chalfont  
PA, 18914-0218  
USA  
Telephone: +1 215 822 8181  
Emergency Tel: +1800 222 1222 (US Only)

Company: Aquarium Pharmaceuticals Incorporated  
Address:  
50 East Hamilton Street  
Chalfont  
PA, 18914  
USA  
Telephone: +1 215 822 8181

### PRODUCT USE

Used according to manufacturers directions. For products 15A and 15B.

### SYNONYMS

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## Section 2 - COMPOSITION / INFORMATION ON INGREDIENTS

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| NAME                                      | CAS RN      | %     |
|---|-------------|-------|
| alpha-lactose                             | 63-42-3     | 30-60 |
| metronidazole                             | 443-48-1    | 30-40 |
| copper sulfate                            | 7758-98-7   | 1-4   |
| trichlorfon                               | 52-68-6     | 1-5   |
| silica amorphous, fumed, crystalline free | 112945-52-5 | 1-5   |
| magnesium stearate                        | 557-04-0    | <1    |

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## Section 3 - HAZARDS IDENTIFICATION

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### CANADIAN WHMIS SYMBOLS



### EMERGENCY OVERVIEW

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Section 3 - HAZARDS IDENTIFICATION

## RISK

May cause CANCER.

May cause SENSITIZATION by skin contact.

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Ingestion may produce health damage\*.

Cumulative effects may result following exposure\*.

May be harmful to the fetus/ embryo\*.

May possibly affect fertility\*.

\*(limited evidence)

## POTENTIAL HEALTH EFFECTS

### ACUTE HEALTH EFFECTS

#### SWALLOWED

Accidental ingestion of the material may be damaging to the health of the individual.

A metallic taste, nausea, vomiting and burning feeling in the upper stomach region occur after ingestion of copper and its derivatives. The vomitus is usually green/blue and discolors contaminated skin. Acute poisonings from ingestion are rare due to their prompt removal by vomiting. Should vomiting not occur, or is delayed systemic poisoning may occur producing kidney and liver damage, wide-spread capillary damage, and be fatal; death may occur after relapse from an apparent recovery. Anemia may occur in acute poisoning. 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.

#### 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).

#### 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.

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 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.

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.

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Section 3 - HAZARDS IDENTIFICATION

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## CHRONIC HEALTH EFFECTS

Imidazole is structurally related to histamine and has been used as an antagonist to counteract the effects of excess histamine found in certain induced physiological conditions (it therefore acts as an antihistamine). Imidazoles have been reported to disrupt male fertility through disruption of testicular function. 2-Methylimidazole decreased luteinising hormone secretion and tissue interstitial fluid testosterone concentration two hours after injection into Sprague Dawley rats. Imidazoles bind to cytochrome P450 haeme, resulting in inhibition of catalysis. However, 2-substituted imidazoles are considered to be poor inhibitors. Imidazole is probably an inducer of cytochrome P4502E1. In general, inducers of this isozyme stabilise the enzyme by preventing phosphorylation of a serine which leads to haeme loss. Several drugs containing an imidazole moiety were retained and bound in connective tissue when administered to laboratory animals. The bound material was primarily recovered from elastin (70%) and the collagen. It is postulated that reaction with aldehydes gives an aldol condensation product. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population. There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information. 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 may cause concerns for human fertility, on the basis that similar materials provide some evidence of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which are not a secondary non-specific consequence of other toxic effects. .

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## Section 4 - FIRST AID MEASURES

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### SWALLOWED

- For advice, contact a Poisons Information Center or a doctor at once.
- Urgent hospital treatment is likely to be needed.
- 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.
- Transport to hospital or doctor without delay.

### 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.

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Section 4 - FIRST AID MEASURES

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- 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.
- Other measures are usually unnecessary.

## NOTES TO PHYSICIAN

Treat symptomatically.

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## Section 5 - FIRE FIGHTING MEASURES

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Flash Point (F): Not Applicable

Lower Explosive Limit (%): Not Applicable

Upper Explosive Limit (%): Not Applicable

Autoignition Temp (F): Not Applicable

## EXTINGUISHING MEDIA

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

## FIRE FIGHTING

- Alert Emergency Responders and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water course.
- Use fire fighting procedures suitable for surrounding 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

- Non combustible.
  - Not considered to be a significant fire risk, however containers may burn.
- Decomposition may produce toxic fumes of, carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), sulfur oxides (SO<sub>x</sub>), 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.

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Section 5 - FIRE FIGHTING MEASURES

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Gloves:  
PVC chemical resistant type.  
Respirator:  
Particulate

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## Section 6 - ACCIDENTAL RELEASE MEASURES

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### MINOR SPILLS

- Clean up all spills immediately.
- Secure load if safe to do so.
- Bundle/collect recoverable product.
- Collect remaining material in containers with covers for disposal.

### MAJOR SPILLS

- Clean up all spills immediately.
- Wear protective clothing, safety glasses, dust mask, gloves.
- Secure load if safe to do so. Bundle/collect recoverable product.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).
- Water may be used to prevent dusting.
- Collect remaining material in containers with covers for disposal.
- Flush spill area with water.

## 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.

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## Section 7 - HANDLING AND STORAGE

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### 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.

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Section 7 - HANDLING AND STORAGE

- 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.

## RECOMMENDED STORAGE METHODS

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

## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

US OSHA Permissible Exposure Levels ( PELs)

| Z  | Material                               | TWA<br>ppm | TWA<br>mg/m <sup>3</sup> | STEL<br>ppm | STEL<br>mg/m <sup>3</sup> | Peak<br>ppm | Peak<br>mg/m <sup>3</sup> | Max<br>excursion<br>ppm | Max<br>excursion<br>mg/m <sup>3</sup> | Max<br>excursion<br>duration<br>(mins) |
|----|--|------------|--------------------------|-------------|---------------------------|-------------|---------------------------|-------------------------|---------------------------------------|--|
| Z1 | Copper - Fume<br>(as Cu)               |            | 0.1                      |             |                           |             |                           |                         |                                       |  |
| Z1 | Copper - Dusts<br>and mists (as<br>Cu) |            | 1                        |             |                           |             |                           |                         |                                       |  |

| Source   | Material                                   | TWA<br>ppm | TWA<br>mg/m <sup>3</sup> | STEL<br>ppm | STEL<br>mg/m <sup>3</sup> | Peak<br>ppm | Peak<br>mg/m <sup>3</sup> |
|--|--|------------|--------------------------|-------------|---------------------------|-------------|---------------------------|
| US - California<br>Permissible Exposure<br>Limits for Chemical<br>Contaminants | Copper salts,<br>dusts and mists,<br>as Cu | --         | 1                        |             |                           |             |                           |
| US - Minnesota<br>Permissible Exposure<br>Limits (PELs)                        | Copper - Dusts<br>and mists (as<br>Cu)     |            | 1                        |             |                           |             |                           |
| Canada Ontario<br>Occupational Exposure  | Copper fume (as<br>copper)                 |            | 0.2                      |             |                           |             |                           |

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

| Z Material  | US OSHA Permissible Exposure Levels ( PELs) |                                   |             | STEL<br>mg/m <sup>3</sup> | Peak<br>ppm | Peak<br>mg/m <sup>3</sup> | Max<br>excursion | Max<br>excursion | Max<br>excursion |
|---|---|-----------------------------------|-------------|---------------------------|-------------|---------------------------|------------------|------------------|------------------|
|   | TWA<br>ppm                                  | TWA<br>mg/m <sup>3</sup>          | STEL<br>ppm |                           |             |                           |                  |                  |                  |
| Limits  |   |                                   |             |                           |             |                           |                  |                  |                  |
| Canada Ontario Occupational Exposure Limits   |   | Copper dust and mists (as copper) |             |                           | 1           |                           |                  |                  |                  |
| US - Minnesota Permissible Exposure Limits (PELs)   |   | Copper - Fume (as Cu)             |             |                           | 0.1         |                           |                  |                  |                  |
| US - Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants   |   | Copper - Fume (as Cu)             |             |                           | 0.1         |                           |                  |                  |                  |
| US - Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants   |   | Copper - Dusts and mists (as Cu)  |             |                           | 1           |                           |                  |                  |                  |
| US - Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants   |   | Copper - Cotton dust (raw)        |             | 1                         |             |                           |                  |                  |                  |
| US - Vermont Permissible Exposure Limits Table Z-1-A Transitional Limits for Air Contaminants |   | Copper - Dusts and mists (as Cu)  |             |                           | 1           |                           |                  |                  |                  |
| US Tennessee Occupational Exposure Limits - Limits For Air Contaminants                       |   | Copper - Fume (as Cu)             |             |                           | 0.1         |                           |                  |                  |                  |
| US Tennessee Occupational Exposure Limits - Limits For Air Contaminants                       |   | Copper - Dusts and mists (as Cu)  |             |                           | 1           |                           |                  |                  |                  |
| US - Vermont Permissible Exposure Limits Table Z-1-A Transitional Limits for Air Contaminants |   | Copper - Fume (as Cu)             |             |                           | 0.1         |                           |                  |                  |                  |
| Canada - Saskatchewan Occupational Health and Safety Regulations - Contamination Limits       |   | Copper dusts and mists, (as Cu)   |             |                           | 1           |                           | 2                |                  |                  |
| US - Washington Permissible exposure limits of air contaminants                               |   | Copper (as Cu) - Dusts and mists  |             |                           | 1           |                           | 3                |                  |                  |
| Canada - Yukon Permissible Concentrations for Airborne Contaminant Substances                 |   | Copper - Fume                     |             | -                         | 0.2         | -                         | 0.2              |                  |                  |
| Canada - Yukon Permissible Concentrations for Airborne Contaminant Substances                 |   | Copper - Dusts and mists (as Cu)  |             | -                         | 1           | -                         | 2                |                  |                  |

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### US OSHA Permissible Exposure Levels (PELs)

| Z | Material   | TWA<br>ppm | TWA<br>mg/m <sup>3</sup>   | STEL<br>ppm | STEL<br>mg/m <sup>3</sup> | Peak<br>ppm | Peak<br>mg/m <sup>3</sup> | Max<br>excursion | Max<br>excursion | Max<br>excursion |
|---|--|------------|--|-------------|---------------------------|-------------|---------------------------|------------------|------------------|------------------|
|   | US - Washington<br>Permissible exposure<br>limits of air<br>contaminants                         |            | Copper (as Cu) -<br>Fume   |             |                           |             | 0.1                       |                  | 0.3              |                  |
|   | Canada - British Columbia<br>Occupational Exposure<br>Limits                                     |            | Copper - Dusts<br>and mists, as Cu   |             |                           | 1           |                           |                  |                  |                  |
|   | Canada - British Columbia<br>Occupational Exposure<br>Limits                                     |            | Copper - Fume,<br>as Cu  |             |                           |             | 0.2                       |                  |                  |                  |
|   | NIOSH Recommended<br>Exposure Limits for<br>Hazardous Agents in the<br>Workplace                 |            | Copper - Dusts<br>and/or mists (as<br>Cu)  |             |                           | 1           |                           |                  |                  |                  |
|   | NIOSH Recommended<br>Exposure Limits for<br>Hazardous Agents in the<br>Workplace                 |            | Copper - Fume<br>(as Cu)   |             |                           |             | 0.1                       |                  |                  |                  |
|   | Canada Ontario<br>Occupational Exposure<br>Limits  |            | Trichlorphon,<br>inhalable   |             |                           |             | 1                         |                  |                  |                  |
|   | Canada - British Columbia<br>Occupational Exposure<br>Limits                                     |            | Trichlorphon,<br>Inhalable<br>(Revised 2003)   |             |                           |             | 1                         |                  |                  |                  |
|   | US - California<br>Permissible Exposure<br>Limits for Chemical<br>Contaminants                   |            | Magnesium<br>stearate  |             | --                        |             | 10                        |                  |                  |                  |
|   | Canada Ontario<br>Occupational Exposure<br>Limits  |            | Stearates (total<br>dust)  |             |                           |             | 10                        |                  |                  |                  |
|   | Canada - British Columbia<br>Occupational Exposure<br>Limits                                     |            | Stearates  |             |                           |             | 10 (J)                    |                  |                  |                  |
|   | Canada - Saskatchewan<br>Occupational Health and<br>Safety Regulations -<br>Contamination Limits |            | Stearates  |             |                           |             | 10                        |                  | 20               |                  |
|   | US - California<br>Permissible Exposure<br>Limits for Chemical<br>Contaminants                   |            | Manganese and<br>compounds, as Mn  |             | --                        |             | 0.2                       |                  |                  |                  |
|   | No data available:   |            | alpha-lactose as (CAS: 63-42-3) / (CAS: 5989-81-1) / (CAS: 14641-93-1) / (CAS: 64044-51-5) / (CAS: 67256-35-3) |             |                           |             |                           |                  |                  |                  |
|   | No data available:   |            | metronidazole as (CAS: 443-48-1)   |             |                           |             |                           |                  |                  |                  |
|   | No data available:   |            | copper sulfate as (CAS: 7758-98-7)   |             |                           |             |                           |                  |                  |                  |
|   | No data available:   |            | silica amorphous, fumed, crystalline free as (CAS: 112945-52-5) / (CAS: 67256-35-3)                            |             |                           |             |                           |                  |                  |                  |

### EMERGENCY EXPOSURE LIMITS

| Material | Revised IDLH<br>Value (ppm) | Revised IDLH<br>Value (mg/m <sup>3</sup> ) |
|----------|-----------------------------|--|
|----------|-----------------------------|--|

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Silica, amorphous 3,000

No data for General Cure Capsules.

### EXPOSURE STANDARDS FOR MIXTURE

"Worst Case" computer-aided prediction of spray/ mist or fume/ dust components and concentration:

"Worst Case" computer-aided prediction of spray/ mist or fume/ dust components and concentration:

Composite Exposure Standard for Mixture (TWA) :2 mg/m<sup>3</sup>.

"Worst Case" computer-aided prediction of spray/ mist or fume/ dust components and concentration:

Composite Exposure Standard for Mixture (TWA) (mg/m<sup>3</sup>):

Operations which produce a spray/mist or fume/dust, introduce particulates to the breathing zone.

If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed. Component Breathing Zone ppm Breathing Zone mg/m<sup>3</sup> Mixture Conc (%).

| Component                          | Breathing Zone<br>(mg/m <sup>3</sup> ) | Mixture Conc<br>(%) |
|------------------------------------|--|---------------------|
| silica amorphous, fumed, crystalli | 2.0000                                 | 5.0                 |

### REPRODUCTIVE HEALTH GUIDELINES

Established occupational exposure limits frequently do not take into consideration reproductive end points that are clearly below the thresholds for other toxic effects. Occupational reproductive guidelines (ORGs) have been suggested as an additional standard. These have been established after a literature search for reproductive no-observed-adverse effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL). In addition the US EPA's procedures for risk assessment for hazard identification and dose-response assessment as applied by NIOSH were used in the creation of such limits.

| Ingredient  | ORG                    | UF  | Endpoint | CR | TLV Adeq |
|-------------|------------------------|-----|----------|----|----------|
| trichlorfon | 0.48 mg/m <sup>3</sup> | 100 | D        | NA | -        |

These exposure guidelines have been derived from a screening level of risk assessment and should not be construed as unequivocally safe limits. ORGS represent an 8-hour time-weighted average unless specified otherwise.

CR = Cancer Risk/10000; UF = Uncertainty factor:

TLV believed to be adequate to protect reproductive health:

LOD: Limit of detection

Toxic endpoints have also been identified as:

D = Developmental; R = Reproductive; TC = Transplacental carcinogen

Jankovic J., Drake F.: A Screening Method for Occupational Reproductive Health Risk: American Industrial Hygiene Association Journal 57: 641-649 (1996).

### INGREDIENT DATA

#### ALPHA-LACTOSE:

Dusts not otherwise classified, as inspirable dust;  
ES TWA: 10 mg/m<sup>3</sup>.

#### METRONIDAZOLE:

Dusts not otherwise classified, as inspirable dust;

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

ES TWA: 10 mg/m<sup>3</sup>.

Particulate (insoluble or poorly soluble \*) Not Otherwise Specified (P.N.O.C)

TLV TWA: 10 mg/m<sup>3</sup> Inhalable particulate

TLV TWA: 3 mg/m<sup>3</sup> Respirable particulate

OEL-Sweden, United Kingdom: 10 mg/m<sup>3</sup> total dust, 5 mg/m<sup>3</sup> respirable dust

These "dusts" have little adverse effect on the lungs and do not produce toxic effects or organic disease. Although there is no dust which does not evoke some cellular response at sufficiently high concentrations, the cellular response caused by P.N.O.C.s has the following characteristics:

- the architecture of the air spaces remain intact,
- scar tissue (collagen) is not synthesised to any degree,
- tissue reaction is potentially reversible.

Extensive concentrations of P.N.O.C.s may:

- seriously reduce visibility,
- cause unpleasant deposits in the eyes, ears and nasal passages,
- contribute to skin or mucous membrane injury by chemical or mechanical action, per se, or by the rigorous skin cleansing procedures necessary for their removal. [ACGIH]

This limit does not apply:

- to brief exposures to higher concentrations
- nor does it apply to those substances that may cause physiological impairment at lower concentrations but for which a TLV has as yet to be determined.

This exposure standard applies to particles which

- are insoluble or poorly soluble\* in water or, preferably, in aqueous lung fluid (if data is available) and
- have a low toxicity (i.e.. are not cytotoxic, genotoxic, or otherwise chemically reactive with lung tissue, and do not emit ionizing radiation, cause immune sensitization, or cause toxic effects other than by inflammation or by a mechanism of lung overload)

\* Notice of intended change.

### COPPER SULFATE:

No data for copper sulfate.

### SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:

TLV TWA: 2 mg/m<sup>3</sup>

ES TWA: 2 mg/m<sup>3</sup>

### MAGNESIUM STEARATE:

The stearates have a low order of acute and chronic toxicity. Intratracheal administration of relatively large doses in rats produce varying degrees of pulmonary damage. Acute, gross inhalation exposure has been associated with clinical pneumonitis. A case of "pneumoconiosis with probable heart failure" has been reported in a rubber worker occupationally exposed to zinc stearate dust for 29 years. Several cases of infants developing respiratory distress and in some instances, acute fatal pneumonitis on aspiration of zinc stearate powder, have been reported.

## PERSONAL PROTECTION

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### 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

Wear chemical protective gloves, eg. PVC.

Wear safety footwear or safety gumboots, eg. Rubber.

NOTE: The material may produce skin sensitisation in predisposed individuals.

Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

### OTHER

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

### RESPIRATOR

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant.

Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

| Breathing<br>Zone Level<br>ppm (volume) | Maximum<br>Protection<br>Factor | Half-face<br>Respirator | Full-Face<br>Respirator |
|---|---------------------------------|-------------------------|-------------------------|
| 1000                                    | 10                              | -1 P                    | -                       |
| 1000                                    | 50                              | -                       | -1 P                    |
| 5000                                    | 50                              | Airline*                | -                       |
| 5000                                    | 100                             | -                       | -2 P                    |
| 10000                                   | 100                             | -                       | -3 P                    |
|   | 100+                            |                         | Airline* *              |

\* - Continuous Flow \*\* - Continuous-flow or positive pressure demand.

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

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

continued...

# GENERAL CURE CAPSULES

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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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 vapours.

- 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. When handling: Quantities of up to 25 grams, an approved respirator with HEPA filters or cartridges should be considered. Quantities of 25 grams to 1 kilogram, a half-face negative pressure, full negative pressure, or powered helmet-type air purifying respirator should be considered. Quantities in excess of 1 kilogram, a full face negative pressure, helmet-type air purifying, or supplied air respirator should be considered. Written procedures, specific to a particular work-place, may replace these recommendations

\* For Class II Biological Safety Cabinets, Types B2 or B3 should be considered. Where only Class I, open fronted Cabinets are available, glove panels may be added, Laminar flow cabinets do not provide sufficient protection when handling these materials unless especially designed to do so.

General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear an approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas.

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## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

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### PHYSICAL PROPERTIES

Mixes with water.

Molecular Weight: Not Applicable

Melting Range (C): Not Applicable

Solubility in water (g/L): Miscible

pH (1% solution): Not Applicable

Volatile Component (%vol): Not Applicable

Relative Vapor Density (air=1): Not Applicable

Lower Explosive Limit (%): Not Applicable

Autoignition Temp (C): Not Applicable

State: Manufactured

Boiling Range (C): Not Applicable

Specific Gravity (water=1): Not Available

pH (as supplied): Not Applicable

Vapor Pressure (kPa): Not Applicable

Evaporation Rate: Not Applicable

Flash Point (C): Not Applicable

Upper Explosive Limit (%): Not Applicable

Decomposition Temp (°C): Not Available

### APPEARANCE

Light blue capsule containing white and blue powder with no odor; soluble in water.

---

## Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

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### CONDITIONS CONTRIBUTING TO INSTABILITY

Product is considered stable and hazardous polymerization will not occur.

continued...

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## Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

### STORAGE INCOMPATIBILITY

Avoid reaction with oxidizing agents.

## Section 11 - TOXICOLOGICAL INFORMATION

### General Cure Capsules

Not available. Refer to individual constituents.

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

#### ALPHA-LACTOSE:

##### TOXICITY

Oral (rat) LD50: >10000 mg/kg

Equivocal tumorigenic agent by RTECS criteria.

##### IRRITATION

Nil Reported

#### METRONIDAZOLE:

##### TOXICITY

Oral (rat) LD50: 3000 mg/kg

Intraperitoneal (mouse) LD50: 2980 mg/kg

Subcutaneous (mouse) LD50: 3640 mg/kg

WARNING: This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans.

Tenth Annual Report on Carcinogens: Substance anticipated to be Carcinogen [National Toxicology Program: U.S. Dep. of Health & Human Services 2002].

##### IRRITATION

Nil Reported

#### COPPER SULFATE:

##### TOXICITY

Oral (human) LDLo: 50 mg/kg

Oral (man) LDLo: 857 mg/kg

Oral (human) TDLo: 11 mg/kg

Oral (rat) LD50: 300 mg/kg

##### IRRITATION

Nil Reported

#### TRICHLORFON:

##### TOXICITY

Oral (rat) LD50: 560 mg/kg

Inhalation (human) TClO: 1.71 mg/m<sup>3</sup>/90d-l

Inhalation (rat) LC50: 1300 mg/m<sup>3</sup>

Dermal (rabbit) LD50: >1500 mg/kg

The substance is classified by IARC as Group 3:

NOT classifiable as to its carcinogenicity to humans.

Evidence of carcinogenicity may be inadequate or limited in animal testing.

ADI: 0.002 mg/kg/day

NOEL: 0.2 mg/kg/day

##### IRRITATION

Eye (rabbit): 120 mg/6d -I- Mild

#### SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:

##### TOXICITY

Oral (rat) LD50: 3160 mg/kg

Dermal (rabbit) LD50: >5000 mg/kg \*

##### IRRITATION

No data

\* [Cabot]

#### MAGNESIUM STEARATE:

Not available. Refer to individual constituents.

MATERIAL

CARCINOGEN

SENSITIZER SKIN

MUTAGEN

REPROTOXIN

continued...

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Section 11 - TOXICOLOGICAL INFORMATION

General Cure Capsules

alpha-lactose

metronidazole

copper sulfate

trichlorfon

Listed

silica amorphous, fumed,

crystalline free

magnesium stearate

CARCINOGEN

ACGIH: trichlorfon: A4

## Section 12 - ECOLOGICAL INFORMATION

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

DO NOT discharge into sewer or waterways.

Refer to data for ingredients, which follows:

**METRONIDAZOLE:**

DO NOT discharge into sewer or waterways.

**COPPER SULFATE:**

Fish LC50 (96hr.) (mg/l): 3.20-7.4

Copper is unlikely to accumulate in the atmosphere due to a short residence time for airborne copper aerosols. Airborne coppers, however, may be transported over large distances. Copper accumulates significantly in the food chain.

The toxic effect of copper in the aquatic biota depends on the bio-availability of copper in water which, in turn, depends on its physico-chemical form (i.e. speciation). Bioavailability is decreased by complexation and adsorption of copper by natural organic matter, iron and manganese hydrated oxides, and chelating agents excreted by algae and other aquatic organisms. Toxicity is also effected by pH and hardness. Total copper is rarely useful as a predictor of toxicity. In natural sea water, more than 98% of copper is organically bound and in river waters a high percentage is often organically bound, but the actual percentage depends on the river water and its pH.

Copper exhibits significant toxicity in some aquatic organisms. Some algal species are very sensitive to copper with EC50 (96 hour) values as low as 47 ug/liter dissolved copper whilst for other algal species EC50 values of up to 481 ug/liter have been reported. However many of the reportedly high EC50 values may arise in experiments conducted with a culture media containing copper-complexing agents such as silicate, iron, manganese and EDTA which reduce bioavailability.

Toxic effects arising following exposure by aquatic species to copper are typically:

Algae  
EC50 (96  
h)

Daphnia  
magna  
LC50

Amphipod  
s LC50  
(48-96

Gastropo  
ds LC50  
(48-96

Crab  
larvae  
LC50

continued...

# GENERAL CURE CAPSULES

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## Section 12 - ECOLOGICAL INFORMATION

|          |              |          |          |              |
|----------|--------------|----------|----------|--------------|
|          | (48-96<br>h) | h)       | h)       | (48-96<br>h) |
| 47-481 * | 7-54 *       | 37-183 * | 58-112 * | 50-100 *     |

\* ug/liter

Exposure to concentrations ranging from one to a few hundred micrograms per liter has led to sublethal effects and effects on long-term survival. For high bioavailability waters, effect concentrations for several sensitive species may be below 10 ug Cu/liter.

In fish, the acute lethal concentration of copper ranges from a few ug/liter to several mg/liter, depending both on test species and exposure conditions. Where the value is less than 50 ug Cu/liter, test waters generally have a low dissolved organic carbon (DOC) level, low hardness and neutral to slightly acidic pH. Sublethal effects and effects on long-term survival range from exposure to concentrations from one to a few hundred ug/liter. Lower effect concentrations are generally associated with test waters of high bioavailability.

In summary:

Responses expected for high concentration ranges of copper \*

|   |   |
|---|---|
| Total dissolved Cu concentration range (ug/liter) | Effects of high availability in water   |
| 1-10  | Significant effects are expected for diatoms and sensitive invertebrates, notably cladocerans. Effects on fish could be significant in freshwaters with low pH and hardness.  |
| 10-100  | Significant effects are expected on various species of microalgae, some species of macroalgae, and a range of invertebrates, including crustaceans, gastropods and sea urchins. Survival of sensitive fish will be affected and a variety of fish show sublethal effects. |
| 100-1000  | Most taxonomic groups of macroalgae and invertebrates will be severely affected. Lethal levels for most fish species will be reached.   |
| >1000   | Lethal concentrations for most tolerant organisms are reached.  |

\* Sites chosen have moderate to high bioavailability similar to water used in most toxicity tests.

In soil, copper levels are raised by application of fertilizer, fungicides, from deposition of highway dusts and from urban, mining and industrial sources. Generally, vegetation rooted in soils reflects the soil copper levels in its foliage. This is dependent upon the bioavailability of copper and the physiological requirements of species concerned.

Typical foliar levels of copper are:

|   |                                       |                           |
|---|---------------------------------------|---------------------------|
| Uncontaminated soils<br>(0.3-250 mg/kg) | Contaminated soils<br>(150-450 mg/kg) | Mining/ smelting<br>soils |
| 6.1-25 mg/kg                            | 80 mg/kg                              | 300 mg/kg                 |

continued...

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Section 12 - ECOLOGICAL INFORMATION

Plants rarely show symptoms of toxicity or of adverse growth effects at normal soil concentrations of copper. Crops are often more sensitive to copper than the native flora, so protection levels for agricultural crops range from 25 mg Cu/kg to several hundred mg/kg, depending on country. Chronic and or acute effects on sensitive species occur at copper levels occurring in some soils as a result of human activities such as copper fertilizer addition, and addition of sludge. When soil levels exceed 150 mg Cu/kg, native and agricultural species show chronic effects. Soils in the range 500-1000 mg Cu/kg act in a strongly selective fashion allowing the survival of only copper-tolerant species and strains. At 2000 Cu mg/kg most species cannot survive. By 3500 mg Cu/kg areas are largely devoid of vegetation cover. The organic content of the soil appears to be a key factor affecting the bioavailability of copper.

On normal forest soils, non-rooted plants such as mosses and lichens show higher copper concentrations. The fruiting bodies and mycorrhizal sheaths of soil fungi associated with higher plants in forests often accumulate copper to much higher levels than plants at the same site. International Programme on Chemical Safety (IPCS): Environmental Health Criteria 200.

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

DO NOT discharge into sewer or waterways.

The material is classified as an ecotoxin\* because the Fish LC50 (96 hours) is less than or equal to 0.1 mg/l

\* Classification of Substances as Ecotoxic (Dangerous to the Environment)

Appendix 8, Table 1

Compiler's Guide for the Preparation of International Chemical Safety Cards:

1993 Commission of the European Communities.

## TRICHLORFON:

Fish LC50 (96hr.) (mg/l): 3.8-4.5

Daphnia magna EC50 (48hr.) (mg/l): 0.00018

Half-life Soil - High (hours): 1080

Half-life Soil - Low (hours): 24

Half-life Air - High (hours): 101

Half-life Air - Low (hours): 1

Half-life Surface water - High (hours): 588

Half-life Surface water - Low (hours): 22

Half-life Ground water - High (hours): 588

Half-life Ground water - Low (hours): 22

Aqueous biodegradation - Aerobic - High (hours): 1080

Aqueous biodegradation - Aerobic - Low (hours): 24

Aqueous biodegradation - Anaerobic - High (hours): 4320

Aqueous biodegradation - Anaerobic - Low (hours): 96

Photolysis maximum light absorption - High (nano-m): <200

Photooxidation half-life air - High (hours): 101

Photooxidation half-life air - Low (hours): 1

First order hydrolysis half-life (hours): 68

Acid rate constant [M(H<sup>+</sup>)-HR]-1: 1.18E-03

Base rate constant [MOH]-HR]-1: 0.0315 HR

The material is classified as an ecotoxin\* because the Daphnia EC50 (48 hours)

continued...

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Section 12 - ECOLOGICAL INFORMATION

is less than or equal to 0.1 mg/l

\* Classification of Substances as Ecotoxic (Dangerous to the Environment)

Appendix 8, Table 1

Compiler's Guide for the Preparation of International Chemical Safety Cards:

1993 Commission of the European Communities.

log Kow: 0.76

SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:

Zebra fish LC50(96hr): 10000 mg/L.

Daphnia magna LC50(24hr): 10000 mg/L.

No adverse effects on water purification plant if removed mechanically.

## Section 13 - DISPOSAL CONSIDERATIONS

### Disposal Instructions

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

- Recycle wherever possible or consult manufacturer for recycling options.

- Consult Waste Management Authority for disposal.

- Bury or incinerate residue at an approved site.

- Recycle containers if possible, or dispose of in an authorized landfill.

Puncture containers to prevent re-use and bury at an authorized landfill.

## Section 14 - TRANSPORTATION INFORMATION

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

## Section 15 - REGULATORY INFORMATION



### RISK

Risk Codes

R43

R45(2)

R50/53

Risk Phrases

May cause SENSITISATION by skin contact.

May cause CANCER.

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### REGULATIONS

US EPCRA Section 313 Chemical List For Reporting Year 2004

Ingredient

CAS

% de minimus

continued...

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Section 15 - REGULATORY INFORMATION

|                |           | concentration |
|----------------|-----------|---------------|
| copper sulfate | 7758-98-7 | 1.0           |
| trichlorfon    | 52-68-6   | 1.0           |

alpha-lactose (CAS: 63-42-3) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US Toxic Substances Control Act (TSCA)

alpha-lactose (CAS: 5989-81-1) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US Toxic Substances Control Act (TSCA)

alpha-lactose (CAS: 14641-93-1) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US Toxic Substances Control Act (TSCA)

alpha-lactose (CAS: 64044-51-5) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US Toxic Substances Control Act (TSCA)

alpha-lactose (CAS: 10039-26-6) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US Toxic Substances Control Act (TSCA)

metronidazole (CAS: 443-48-1) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US - California Occupational Safety and Health Regulations (CAL/OSHA) -

Hazardous Substances List

US - California Proposition 65 - Carcinogens

US - California Proposition 65 - Priority List for the Development of NSRLs for

Carcinogens

US - Minnesota Hazardous Substance List

US National Toxicology Program (NTP) 11th Report Part B. Reasonably Anticipated

to be a Human Carcinogen

copper sulfate (CAS: 7758-98-7) is found on the following regulatory lists;

US - California Occupational Safety and Health Regulations (CAL/OSHA) -

Hazardous Substances List

US EPCRA Section 313 Chemical List For Reporting Year 2004

trichlorfon (CAS: 52-68-6) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US - California Occupational Safety and Health Regulations (CAL/OSHA) -

Hazardous Substances List

US ACGIH Carcinogens Listing

US CWA (Clean Water Act) - List of Hazardous Substances

US CWA (Clean Water Act) - Reportable Quantities of Designated Hazardous

Substances

US EPA Hazardous Substances

US EPCRA Section 313 Chemical List For Reporting Year 2004

silica amorphous, fumed, crystalline free (CAS: 112945-52-5) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US EPA High Production Volume Chemicals Additional List

magnesium stearate (CAS: 557-04-0) is found on the following regulatory lists;

Canada Domestic Substances List (DSL)

US - Minnesota Hazardous Substance List

US EPA High Production Volume Program Chemical List

continued...

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Section 15 - REGULATORY INFORMATION

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US Toxic Substances Control Act (TSCA)

No data available for silica amorphous, fumed, crystalline free as CAS:  
67256-35-3.

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## Section 16 - OTHER INFORMATION

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### LIMITED EVIDENCE

Ingestion may produce health damage\*.

Cumulative effects may result following exposure\*.

May be harmful to the foetus/ embryo\*.

May possibly affect fertility\*.

\* (limited evidence).

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