GENERAL CURE POWDER MEDICATION

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

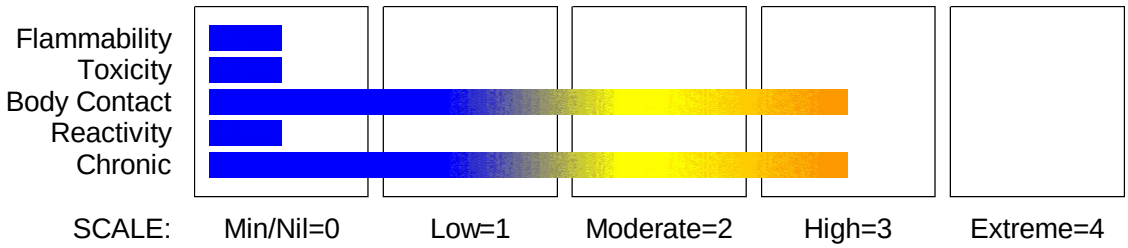
PRODUCT NAME
GENERAL CURE POWDER MEDICATION

PRODUCT USE
■ Used according to manufacturer's directions.

SUPPLIER
Company: Mars Fishcare Inc
Address:
50 East Hamilton Street
Chalfont
PA, 18914
USA
Telephone: +1 215 822 8181
Fax: +1 215 822 1906

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS



GHS Classification
Acute Aquatic Hazard Category 3
Acute Toxicity (Oral) Category 5
Aspiration Hazard Category 1
Carcinogen Category 1B
Chronic Aquatic Hazard Category 3
Organ Damage Category 2
Reproductive Toxicity Category 2
Respiratory Effects Category 3
Respiratory Irritation Category 3
Serious Eye Damage Category 1
Skin Corrosion/Irritation Category 2

continued...

EMERGENCY OVERVIEW

HAZARD
DANGER
Determined by Chemwatch using GHS criteria:
H335 H336 H303 H304 H350 H361 H361 H373 H318 H402 H412 H315 H318
May cause respiratory irritation
May cause drowsiness or dizziness
May be harmful if swallowed
May be fatal if swallowed and enters airways
May cause CANCER
Suspected of damaging fertility
Suspected of damaging the unborn child
May cause damage to organs through prolonged or repeated exposure.
Causes serious eye damage
Harmful to aquatic life
Harmful to aquatic life with long lasting effects
Causes skin irritation
Causes serious eye damage

PRECAUTIONARY STATEMENTS

Prevention
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection.
Use personal protective equipment as required.

Response
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/ attention.
Immediately call a POISON CENTER or doctor/physician.
Call a POISON CENTER or doctor/physician if you feel unwell.
Get medical advice/attention if you feel unwell.
Do NOT induce vomiting.

continued...

Storage
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
sodium chloride	7647-14-5	>80
metronidazole	443-48-1	1-10
praziquantel	55268-74-1	1-5
silica amorphous, fumed, crystalline free	112945-52-5	1-5

Section 4 - FIRST AID MEASURES

SWALLOWED
• Immediately give a glass of water.
• First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

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.
• Seek medical attention without delay; if pain persists or recurs seek medical attention.
• Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN
■ If skin contact occurs:
• Immediately remove all contaminated clothing, including footwear.
• Flush skin and hair with running water (and soap if available).
• Seek medical attention in event of irritation.

INHALED
• If fumes or combustion products are inhaled remove from contaminated area.
• Other measures are usually unnecessary.

NOTES TO PHYSICIAN
■ Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

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

FIRE/EXPLOSION HAZARD
• Non combustible.
• Not considered a significant fire risk, however containers may burn.
Decomposition may produce toxic fumes of: nitrogen oxides (NOx), metal oxides.

continued...

May emit poisonous fumes.
May emit corrosive fumes, hydrogen chloride.

FIRE INCOMPATIBILITY
■ None known.

PERSONAL PROTECTION

Glasses:	Gloves:	Respirator:
Chemical goggles.	PVC chemical resistant type.	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.

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

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.

SUITABLE CONTAINER
• Polyethylene or polypropylene container.
• Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS
• Store in original containers.

continued...

- Keep containers securely sealed.
- Store in a cool, dry area protected from environmental extremes.
- 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

For major quantities:

- Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams}.
- Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS

X	X	+	X	X	+

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

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

US OSHA Permissible Exposure Levels (PELs)

Z	Material	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³	Peak ppm	Peak mg/m³	Max excursion ppm	Max excursion mg/m³	Max excursion duration (mins)	TWA F/CC
Z3	Inert or Nuisance Dust: (d) Respirable fraction		5								
Z3	Inert or Nuisance Dust: (d) Total dust		15								
Z3	Inert or Nuisance Dust: (d) Respirable fraction		5								
Z3	Inert or Nuisance Dust: (d) Total dust		15								
Z3	Inert or Nuisance Dust: (d) Respirable fraction		5								
Z3	Inert or Nuisance Dust: (d) Total dust		15								

Source	Material	TWA mg/m³	Notes
US - Oregon Permissible Exposure Limits (Z3)	sodium chloride (Inert or Nuisance Dust: (d) Total dust)	10	*

continued...

Source	Material	TWA mg/m³	Notes
US OSHA Permissible Exposure Levels (PELs) - Table Z3	sodium chloride (Inert or Nuisance Dust: (d) Respirable fraction)	5	
US OSHA Permissible Exposure Levels (PELs) - Table Z3	sodium chloride (Inert or Nuisance Dust: (d) Total dust)	15	
US - Hawaii Air Contaminant Limits	sodium chloride (Particulates not other wise regulated - Total dust)	10	
US - Hawaii Air Contaminant Limits	sodium chloride (Particulates not other wise regulated - Respirable fraction)	5	
US - Oregon Permissible Exposure Limits (Z3)	sodium chloride (Inert or Nuisance Dust: (d) Respirable fraction)	5	*
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	sodium chloride (Particulates not otherwise regulated Respirable fraction)	5	
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	sodium chloride (Particulates not otherwise regulated (PNOR)(f)- Respirable fraction)	5	
US - Michigan Exposure Limits for Air Contaminants	sodium chloride (Particulates not otherwise regulated, Respirable dust)	5	
US - Oregon Permissible Exposure Limits (Z3)	metronidazole (Inert or Nuisance Dust: (d) Total dust)	10	*
US OSHA Permissible Exposure Levels (PELs) - Table Z3	metronidazole (Inert or Nuisance Dust: (d) Respirable fraction)	5	
US OSHA Permissible Exposure Levels (PELs) - Table Z3	metronidazole (Inert or Nuisance Dust: (d) Total dust)	15	
US - Hawaii Air Contaminant Limits	metronidazole (Particulates not other wise regulated - Total dust)	10	
US - Hawaii Air Contaminant Limits	metronidazole (Particulates not other wise regulated - Respirable fraction)	5	
US - Oregon Permissible Exposure Limits (Z3)	metronidazole (Inert or Nuisance Dust: (d) Respirable fraction)	5	*
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	metronidazole (Particulates not otherwise regulated Respirable fraction)	5	
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	metronidazole (Particulates not otherwise regulated (PNOR)(f)- Respirable fraction)	5	
US - Michigan Exposure Limits for Air Contaminants	metronidazole (Particulates not otherwise regulated, Respirable dust)	5	
US - Oregon Permissible Exposure Limits (Z3)	silica amorphous, fumed, crystalline free (Inert or Nuisance Dust: (d) Total dust)	10	*

continued...

Source	Material	TWA mg/m³	Notes
US - Oregon Permissible Exposure Limits (Z3)	silica amorphous, fumed, crystalline free (Inert or Nuisance Dust: (d) Respirable fraction)	5	*
US OSHA Permissible Exposure Levels (PELs) - Table Z3	silica amorphous, fumed, crystalline free (Inert or Nuisance Dust: (d) Total dust)	15	
US OSHA Permissible Exposure Levels (PELs) - Table Z3	silica amorphous, fumed, crystalline free (Inert or Nuisance Dust: (d) Respirable fraction)	5	
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US - Hawaii Air Contaminant Limits	silica amorphous, fumed, crystalline free (Particulates not other wise regulated - Respirable fraction)	5	
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	silica amorphous, fumed, crystalline free (Particulates not otherwise regulated (PNOR)(f)- Respirable fraction)	5	
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	silica amorphous, fumed, crystalline free (Particulates not otherwise regulated Respirable fraction)	5	
US - Michigan Exposure Limits for Air Contaminants	silica amorphous, fumed, crystalline free (Particulates not otherwise regulated, Respirable dust)	5	
Canada - Alberta Occupational Exposure Limits	silica amorphous, fumed, crystalline free (Particulate Not Otherwise Regulated - Respirable)	3	
US - Oregon Permissible Exposure Limits (Z1)	silica amorphous, fumed, crystalline free (Particulates not otherwise regulated (PNOR) (f) Respirable Fraction)	5	*
Canada - Northwest Territories Occupational Exposure Limits (English)	silica amorphous, fumed, crystalline free (Silica - Silica Flour (Total Mass))	0.15	

The following materials had no OELs on our records
• praziquantel: CAS:55268- 74- 1

EMERGENCY EXPOSURE LIMITS

Material	Revised IDLH Value (mg/m3)	Revised IDLH Value (ppm)
silica amorphous, fumed, crystalline free	3, 000	

continued...

MATERIAL DATA

GENERAL CURE POWDER MEDICATION:

Not available

SODIUM CHLORIDE:

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

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

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

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

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

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

METRONIDAZOLE:

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continued...

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- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

PRAZIQUANTEL:

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

SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:

■ The concentration of dust, for application of respirable dust limits, is to be determined from the fraction that penetrates a separator whose size collection efficiency is described by a cumulative log-normal function with a median aerodynamic diameter of 4.0 µm (+-) 0.3 µm and with a geometric standard deviation of 1.5 µm (+-) 0.1 µm, i.e..generally less than 5 µm.

For amorphous crystalline silica (precipitated silicic acid):

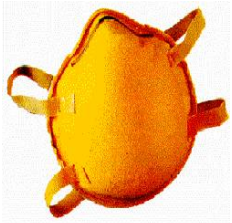
Amorphous crystalline silica shows little potential for producing adverse effects on the lung and exposure standards should reflect a particulate of low intrinsic toxicity. Mixtures of amorphous silicas/ diatomaceous earth and crystalline silica should be monitored as if they comprise only the crystalline forms.

The dusts from precipitated silica and silica gel produce little adverse effect on pulmonary functions and are not known to produce significant disease or toxic effect.

IARC has classified silica, amorphous as Group 3: NOT classifiable as to its carcinogenicity to humans.

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

PERSONAL PROTECTION

EYE

- Safety glasses with side shields.
- Chemical goggles.
- 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

■ Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

continued...

• polychloroprene
• nitrile rubber
• butyl rubber
• fluorocaoutchouc
• polyvinyl chloride
Gloves should be examined for wear and/ or degradation constantly.
• Wear chemical protective gloves, eg. PVC.
• Wear safety footwear or safety gumboots, eg. Rubber.

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

RESPIRATOR

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

* - Negative pressure demand ** - Continuous flow.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

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

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

continued...

Within each range the appropriate value depends on:

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

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated 2 metres 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

APPEARANCE
Off-white powder with a distinctive odour; soluble in water.

PHYSICAL PROPERTIES
Mixes with water.

State	Divided Solid	Molecular Weight	Not Applicable
Melting Range (°F)	Not Applicable	Viscosity	Not Applicable
Boiling Range (°F)	Not Applicable	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not Applicable	pH (1% solution)	Not Applicable
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not Applicable
Autoignition Temp (°F)	Not Applicable	Vapour Pressure (mmHG)	Not Applicable
Upper Explosive Limit (%)	Not Applicable	Specific Gravity (water=1)	1.01
Lower Explosive Limit (%)	Not Applicable	Relative Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Not Applicable	Evaporation Rate	Not Applicable

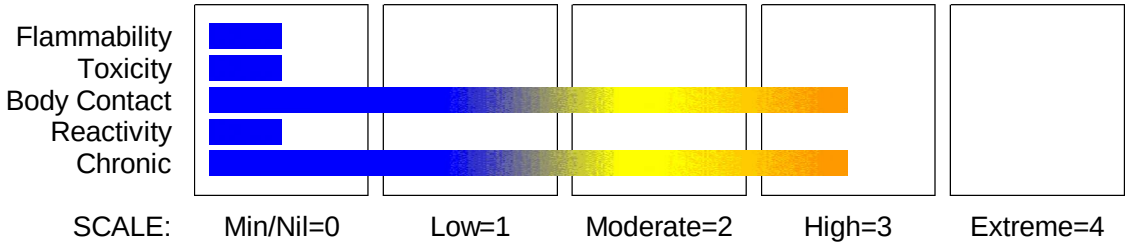
Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY
• Presence of incompatible materials.
• Product is considered stable.
• Hazardous polymerisation will not occur.
For incompatible materials - refer to Section 7 - Handling and Storage.

continued...

Section 11 - TOXICOLOGICAL INFORMATION

CHEMWATCH HAZARD RATINGS



POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED
■ The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (eg. liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

EYE
■ If applied to the eyes, this material causes severe eye damage.
■ There is some evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation. Moderate inflammation may be expected with redness; conjunctivitis may occur with prolonged exposure.

SKIN
■ There is some evidence to suggest that the material may cause mild but significant inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering.
■ 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
■ There is some evidence to suggest that this material, if inhaled, can irritate the throat and lungs of some persons.
■ The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives 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.
■ Not normally a hazard due to non-volatile nature of product.

CHRONIC HEALTH EFFECTS
■ Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray.
Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

continued...

There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information.
Based on experience with similar materials, there is a possibility that exposure to the material may reduce fertility in humans at levels which do not cause other toxic effects.

TOXICITY AND IRRITATION
■ Not available. Refer to individual constituents.

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

TOXICITY
Oral (rat) LD50: 3000 mg/kg
Oral (human) TDLo: 12357 mg/kg/23d
Intravenous (Mouse) LD50: 645 mg/kg
Oral (Human) TDLo: 12357 mg/kg
Subcutaneous (Rat) LD: 3500 mg/kg
Intraperitoneal (Mouse) LD50: 2602 mg/kg
Intravenous (Rabbit) LD: 1100 mg/kg
Subcutaneous (Guinea pig) LD: 2160 mg/kg
Intravenous (Guinea pig) LD: 300 mg/kg
Intraperitoneal (Rat) LD50: 2600 mg/kg

IRRITATION
Skin (rabbit): 500 mg/24h - Mild
Eye (rabbit): 10 mg - Moderate
Eye (rabbit):100 mg/24h - Moderate

■ The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.
Oral Lowest Toxic Dose (Human): 8.2 mg/kg

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

TOXICITY
Oral (rat) LD50: 3000 mg/kg
Intraperitoneal (mouse) LD50: 2980 mg/kg
Subcutaneous (mouse) LD50: 3640 mg/kg

IRRITATION
Nil Reported

■ 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].

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

continued...

TOXICITY
Oral (rat) LD50: 2840 mg/kg
Intraperitoneal (rat) LD50: 586 mg/kg
Subcutaneous (rat) LD50: >16000 mg/kg
Intramuscular (rat) LD50: >2000 mg/kg
Oral (mouse) LD50: 2454 mg/kg
Intraperitoneal (mouse) LD50: 376 mg/kg
Subcutaneous (mouse) LD50: 7172 mg/kg
Intramuscular (mouse) LD50: >2000 mg/kg
Oral (dog) LD50: >200 mg/kg
Oral (rabbit) LD50: 1050 mg/kg

IRRITATION
Nil Reported

■ NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.
* Bayer
ADI: 0.02 mg/kg/day
NOEL: 20 mg/kg/day

SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:
■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY
Oral (rat) LD50: 3160 mg/kg * [Cabot]
Dermal (Rabbit) LD50: >5000 mg/kg *

IRRITATION

■ For silica amorphous:
When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals.
After ingestion, there is limited accumulation of SAS in body tissues and rapid elimination occurs.
Intestinal absorption has not been calculated, but appears to be insignificant in animals and humans. SASs injected subcutaneously are subjected to rapid dissolution and removal. There is no indication of metabolism of SAS in animals or humans based on chemical structure and available data. In contrast to crystalline silica, SAS is soluble in physiological media and the soluble chemical species that are formed are eliminated via the urinary tract without modification.
Both the mammalian and environmental toxicology of SASs are significantly influenced by the physical and chemical properties, particularly those of solubility and particle size. SAS has no acute intrinsic toxicity by inhalation. Adverse effects, including suffocation, that have been reported were caused by the presence of high numbers of respirable particles generated to meet the required test atmosphere. These results are not representative of exposure to commercial SASs and should not be used for human risk assessment. Though repeated exposure of the skin may cause dryness and cracking, SAS is not a skin or eye irritant, and it is not a sensitiser.
Repeated-dose and chronic toxicity studies confirm the absence of toxicity when SAS is swallowed or upon skin contact.
Long-term inhalation of SAS caused some adverse effects in animals (increases in lung inflammation, cell injury and lung collagen content), all of which subsided after exposure.
Numerous repeated-dose, subchronic and chronic inhalation toxicity studies have been conducted with SAS in a number of species, at airborne concentrations ranging from 0.5 mg/m3 to 150 mg/m3. Lowest-observed adverse effect levels (LOAELs) were typically in the range of 1 to 50 mg/m3. When available, the no-observed adverse effect levels (NOAELs) were between 0.5 and 10 mg/m3. The difference in values may be explained by different particle size, and therefore the number of particles administered per unit dose. In general, as particle size decreases so does the NOAEL/LOAEL.
Neither inhalation nor oral administration caused neoplasms (tumours). SAS is not mutagenic in vitro. No genotoxicity was detected in in vivo assays. SAS does not impair development of the foetus. Fertility was not specifically studied, but the reproductive organs in long-term studies were not affected.
In humans, SAS is essentially non-toxic by mouth, skin or eyes, and by inhalation. Epidemiology studies show

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little evidence of adverse health effects due to SAS. Repeated exposure (without personal protection) may cause mechanical irritation of the eye and drying/cracking of the skin.
There is no evidence of cancer or other long-term respiratory health effects (for example, silicosis) in workers employed in the manufacture of SAS. Respiratory symptoms in SAS workers have been shown to correlate with smoking but not with SAS exposure, while serial pulmonary function values and chest radiographs are not adversely affected by long-term exposure to SAS.

CARCINOGEN

Metronidazole	International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs	Group	2B
METRONIDAZOLE	US Environmental Defense Scorecard Recognized Carcinogens	Reference(s)	P65
METRONIDAZOLE	US Environmental Defense Scorecard Suspected Carcinogens	Reference(s)	P65
SILICA	US Environmental Defense Scorecard Recognized Carcinogens	Reference(s)	P65
SILICA	US Environmental Defense Scorecard Suspected Carcinogens	Reference(s)	P65

Section 12 - ECOLOGICAL INFORMATION

metronidazole 72 or 96hr ErC50 (12.5) mg/L Green algae Plant Source: Experimental

Refer to data for ingredients, which follows:

SODIUM CHLORIDE:
METRONIDAZOLE:
PRAZIQUANTEL:
SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:
GENERAL CURE POWDER MEDICATION:
■ DO NOT discharge into sewer or waterways.

GENERAL CURE POWDER MEDICATION:

SODIUM CHLORIDE:
■ Although inorganic chloride ions are not normally considered toxic they can exist in effluents at acutely toxic levels (chloride >3000 mg/l). the resulting salinity can exceed the tolerances of most freshwater organisms.
Inorganic chlorine eventually finds its way into the aqueous compartment and as such is bioavailable. Incidental exposure to inorganic chloride may occur in occupational settings where chemicals management policies are improperly applied. The toxicity of chloride salts depends on the counter-ion (cation) present; that of chloride itself is unknown. Chloride toxicity has not been observed in humans except in the special case of impaired sodium chloride metabolism, e.g. in congestive heart failure. Healthy individuals can tolerate the intake of large quantities of chloride provided that there is a concomitant intake of fresh water.

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Although excessive intake of drinking-water containing sodium chloride at concentrations.
above 2.5 g/litre has been reported to produce hypertension, this effect is believed to be related to the sodium ion concentration.
Chloride concentrations in excess of about 250 mg/litre can give rise to detectable taste in water, but the threshold depends upon the associated cations. Consumers can, however, become accustomed to concentrations in excess of 250 mg/litre. No health-based guideline value is proposed for chloride in drinking-water.
In humans, 88% of chloride is extracellular and contributes to the osmotic activity of body fluids. The electrolyte balance in the body is maintained by adjusting total dietary intake and by excretion via the kidneys and gastrointestinal tract. Chloride is almost completely absorbed in normal individuals, mostly from the proximal half of the small intestine. Normal fluid loss amounts to about 1.5?2 liters/day, together with about 4 g of chloride per day. Most (90 - 95%) is excreted in the urine, with minor amounts in faeces (4- %) and sweat (2%).
Chloride increases the electrical conductivity of water and thus increases its corrosivity. In metal pipes, chloride reacts with metal ions to form soluble salts thus increasing levels of metals in drinking-water. In lead pipes, a protective oxide layer is built up, but chloride enhances galvanic corrosion. It can also increase the rate of pitting corrosion of metal pipes.
TLm 96 > 1000 ppm

METRONIDAZOLE:
■ Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
■ 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.
■ For azole-containing substances.
Azole fungicides and systemically used antifungal drugs directly interfere with steroidogenesis by acting as potent inhibitors of steroidogenic enzymes and are known to cause endocrine disruption mainly via this mechanism.

An important P450 enzyme involved in the steroidogenesis is aromatase. Aromatase demethylates C10 and specifically converts androstenedione and testosterone. On the protein level, the amino acid sequence homology between aromatase from fish and humans is about 50% and between rats and humans is about 78%. In mammals, aromatase is mainly expressed in the brain and the gonads, but it is also found in placental, adipose, and bone tissue. The physiologic balance between different sex steroid hormones is crucial for the development, maintenance, and function of the reproductive system as well as for the differentiation of the sexual phenotype during ontogeny. Oestrogens (estrone and estradiol) are products of the androgens (androstenedione and testosterone), and the reaction is catalysed by aromatase. In mammals, differentiation of the male phenotype depends not only on testosterone but also on estradiol generated from testosterone by neuronal aromatase in central nervous system. Therefore, disturbances in aromatase expression and/or changes in its catalytic activity are expected to exhibit negative effects on reproduction parameters.

Azole-containing compounds produce profound effects in the environment. In part this is due to inhibition of several enzyme systems including those involving sterol 14[alpha]-demethylase. Sterol 14[alpha]-demethylase is a member of the superfamily of haeme-containing cytochrome P450 enzymes involved in metabolism of endogenous and xenobiotic substances. The antifungal effect of azoles is due to inhibition of sterol 14[alpha]-demethylase in fungi and yeast, thereby blocking the biosynthesis of ergosterol The subsequent lack of ergosterol is detrimental because ergosterol is an essential sterol component in the membranes of fungi and yeast. Sterol 14[alpha]-demethylase is not only expressed in fungi and yeast but is also found in many other species ranging from bacteria to mammals. In plants, the sterol 14[alpha]-demethylase reaction metabolises obtusifoliol and provides precursors for biosynthesis of phytosterols. In animals, the sterol 14[alpha]-demethylase reaction is part of the metabolic pathway leading to biosynthesis of cholesterol. Cholesterol in turn is the substrate for the production of many other sterols (e.g., the sex steroid hormones).

The DNA sequences encoding sterol 14[alpha]-demethylase of many fungi and yeast are known, as well as the sequences of mice, rats, pigs, and humans. On the protein level, the amino acid sequences are highly

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conserved along the phylogenetic tree. This fact is considered by many authors as an indication of the pivotal role of sterol 14[alpha]-demethylase in all organisms. The homology of the amino acid sequence level between rats and humans is 93% and 40% between fungi and humans. In humans, the sterol 14[alpha]-demethylase is expressed in many different tissues.

PRAZIQUANTEL:
■ WGK: Classification in accordance with German Water Resources Act.
Ecotoxicology:
Fish LC0 (96 h): Zebra barbel (Brachydanio rerio) 31.6 mg/l
LC100 (96 h): " " " 100 mg/l
Daphnia EC50 (48 h): 35 mg/l
EC100 (48 h): 100 mg/l
Bacterial toxicity EC50: >10000 mg/l; activated sludge
Water pollution class (WGK): 1 - slight water hazard (Bayer classification)

SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:
■ For silica amorphous:
Amorphous silica is chemically and biologically inert. It is not biodegradable. Due to its insolubility in water there is a separation at every filtration and sedimentation process.]
Crystalline and/or amorphous silicas are ubiquitous on the earth in soils and sediments, and in living organisms (e.g. diatoms), but only the dissolved form is bioavailable. On a global scale, the level of man-made synthetic amorphous silicas (SAS) represents up to 2.4% of the dissolved silica naturally present in the aquatic environment. The rate of SAS released into the environment during the product life cycle is negligible in comparison with the natural flux of silica in the environment
Untreated SASs have a relatively low water solubility of 1.91 to 2.51 mmol/l (114 - 151 mg/l) and an extremely low vapour pressure (e.g. < 10–3 Pa at 20° C for Aerosil R972). On the basis of these properties it is expected that SAS released into the environment will be distributed mainly into soil/sediment, slightly into water, and probably not at all into air.
With surface-treated SASs, the addition of organosilicon compounds increases the hydrophobicity. Consequently, the water solubility is lower than that of untreated silica. The vapour pressure remains extremely low. Due to the presence of organic substances such as surfactants, salts, acids and alkalis in the environment, it is expected that surface-treated silica will be wetted and then adsorbed onto soils or sediments.
SAS is regarded as an inert substance and is not expected to undergo any transformation in the atmospheric or terrestrial compartment, apart from dissolution by water.
Biodegradability in sewage treatment plant or in surface water is not applicable to inorganic substances like SAS. Therefore the biodegradation endpoint has limited relevance for SAS. In surface modified SASs, the most common treating agents are organosilicon compounds and these generally represent less than 5% of the material. Biodegradation in sewage treatment plant or in surface water is not expected. Some biodegradation in soil may occur by analogy with the behaviour of linear polydimethylsiloxane in this compartment
Ecotoxicity:
Based on available data, SAS is not toxic to environmental organisms (apart from physical desiccation in insects). SAS presents a low risk for adverse effects to the environment.
When hydrophilic SASs (Aerosil 200 and Ultrasil VN3; purity 100% and 98%, respectively), were tested for their acute toxicity to fish and crustaceans, the LC50 and EC50 values were higher than 10,000 mg/l and 1,000 mg/l, respectively.
The zebra fish (Brachydanio rerio) test was performed with SAS in suspension, due to the insolubility of the SAS. No mortality was observed for the fish after 96 hours of exposure at 1,000 mg/l and 10,000 mg/l. The test media remained turbid throughout the test, indicating that the limit of solubility of the product was exceeded.
With the water flea (Daphnia magna), SAS suspensions exceeding the limit of solubility were tested.; some immobilisation was observed. However, no significant immobilisation was observed when a solution filtered through microfibre glass filter was tested. The observed effects were likely caused by physical hampering of the Daphnia due to the presence of undissolved particles.
A surface-treated SAS (Aerosil R974; 99.9% pure) was tested on fish and crustaceans. The LC50 to fish and EC50 to Daphnia were found to be higher than 10,000 mg/l and 1,000 mg/l, respectively

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The EC50 to algae was found to be higher than 10,000 mg/l filtered suspension The actual dissolved concentrations were not determined. There was no inhibition of the biomass or of the growth rate with the 10, 000 mg/l filtered suspension.
The antibacterial effect of pressed and unpressed high purity SAS (Aerosil, unspecified) (0.2 g silica + 0.15 ml bacteria strain suspension) kept at 22 C has been investigated (SAS is sometimes pressed to remove air before transportation). The following micro-organisms were studied: Escherichia coli, Proteus sp., Pseudomonas aeruginosa, Aerobacter aerogenes,
Micrococcus pyrogenes aureus, Streptococcus faecalis, Streptococcus pyrogenes humans, Corynebacterium diphtheria, Candida albicans and Bacillus subtilis. The SAS was contaminated either by hand contact, by saliva droplets or by contact with the atmosphere. Rodshaped gram-negative organisms (Escherichia coli, Bacterium proteus, Pseudomonas aeruginosa
and Aerobacter aerogenes) died between 6 hours and 3 days in contact with unpressed SAS. Gram-positive micro-organisms were somewhat more resistant. In addition, the tests demonstrated that survival of bacteria was shorter in unpressed than in pressed SAS.
■ For silica:
The literature on the fate of silica in the environment concerns dissolved silica in the aquatic environment, irrespective of its origin (man-made or natural), or structure (crystalline or amorphous). Indeed, once released and dissolved into the environment no distinction can be made between the initial forms of silica. At normal environmental pH, dissolved silica exists exclusively as monosilicic acid [Si(OH)4]. At pH 9.4 the solubility of amorphous silica is about 120 mg SiO2/l . Quartz has a solubility of only 6 mg/l, but its rate of dissolution is so slow at ordinary temperature and pressure that the solubility of amorphous silica represents the upper limit of dissolved silica concentration in natural waters Moreover, silicic acid is the bioavailable form for aquatic organisms and it plays an important role in the biogeochemical cycle of Si, particularly in the oceans.
In the oceans, the transfer of dissolved silica from the marine hydrosphere to the biosphere initiates the global biological silicon cycle. Marine organisms such as diatoms, silicoflagellates and radiolarians build up their skeletons by taking up silicic acid from seawater. After these organisms die, the biogenic silica accumulated in them partly dissolves. The portion of the biogenic silica that does not dissolve settles and ultimately reaches the sediment. The transformation of opal (amorphous biogenic silica) deposits in sediments through diagenetic processes allows silica to re-enter the geological cycle. Silica is labile between the water and sediment interface
Ecotoxicity:
Fish LC50 (96 h): Brachydanio rerio >10000 mg/l; zebra fish >10000 mg/l
Daphnia magna EC50 (24 h): >1000 mg/l; LC50 924 h): >10000 mg/l.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
sodium chloride	LOW		LOW	HIGH
metronidazole	HIGH		LOW	HIGH

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle where possible
  Otherwise ensure that:
- licenced contractors dispose of the product and its container.
- disposal occurs at a licenced facility.

continued...

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

REGULATIONS

Regulations for ingredients

sodium chloride (CAS: 7647-14-5) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)","Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS (English)","Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS (French)","OECD Representative List of High Production Volume (HPV) Chemicals","US DOE Temporary Emergency Exposure Limits (TEELs)","US Food Additive Database","US Toxic Substances Control Act (TSCA) - Inventory"

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

"Canada Domestic Substances List (DSL)","Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS (English)","Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS (French)","International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs","US - California Air Toxics ""Hot Spots"" List (Assembly Bill 2588) Substances which need not be reported unless manufactured by the facility","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 - Connecticut Hazardous Air Pollutants","US - Maine Chemicals of High Concern List","US - Minnesota Hazardous Substance List","US - New Jersey Right to Know Hazardous Substances","US - Pennsylvania - Hazardous Substance List","US - Rhode Island Hazardous Substance List","US National Toxicology Program (NTP) 11th Report Part B. Reasonably Anticipated to be a Human Carcinogen"

silica amorphous, fumed, crystalline free (CAS: 112945-52-5,67256-35-3) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)","Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS (English)", "International Council of Chemical Associations (ICCA) - High Production Volume List","OECD Representative List of High Production Volume (HPV) Chemicals","US DOE Temporary Emergency Exposure Limits (TEELs)","US EPA High Production Volume Chemicals Additional List"

No data for General Cure Powder Medication (CW: 4658-74)

No data for praziquantel (CAS: , 55268-74-1)

Section 16 - OTHER INFORMATION

Denmark Advisory list for selfclassification of dangerous substances

Substance	CAS	Suggested codes
metronidazole	443- 48- 1	Xn Mut3; R68
praziquantel	55268- 74- 1	Xn Mut3; R68 Repr3; R63

INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
silica amorphous, fumed, crystalline free	112945- 52- 5, 67256- 35- 3

CONTACT

Mars Fishcare

■ 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.

continued...

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.

■ For detailed advice on Personal Protective Equipment, refer to the following U.S. Regulations and Standards:
OSHA Standards - 29 CFR:
1910.132 - Personal Protective Equipment - General requirements
1910.133 - Eye and face protection
1910.134 - Respiratory Protection
1910.136 - Occupational foot protection
1910.138 - Hand Protection
Eye and face protection - ANSI Z87.1
Foot protection - ANSI Z41
Respirators must be NIOSH approved.

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