

EM POWDER MEDICATION

Chemwatch GHS Safety Data Sheet
For Domestic Use Only.
Dec-23-2009
NC614TDP

CHEMWATCH 4658-75
Version No:4
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Section 2 - HAZARDS IDENTIFICATION

HAZARD

DANGER

Determined by Chemwatch using GHS criteria:
H335 H303 H316 H320 H334 H317 H316 H320
May cause respiratory irritation
May be harmful if swallowed
Causes mild skin irritation
Causes eye irritation
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled
May cause allergic skin reaction
Causes mild skin irritation
Causes eye irritation

PRECAUTIONARY STATEMENTS

Prevention

Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.

Response

IF ON SKIN: Wash with plenty of soap and water.
IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.
IF INHALED: If breathing is difficult, 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.
Call a POISON CENTER or doctor/physician if you feel unwell.
If skin irritation occurs: Get medical advice/attention.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Wash contaminated clothing before reuse.

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
erythromycin phosphate	4501-00-2	1-10
silica amorphous, fumed, crystalline free	112945-52-5	1-5

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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 (NO_x), metal oxides.
May emit poisonous fumes.
May emit corrosive fumes, hydrogen chloride.

FIRE INCOMPATIBILITY

None known.

PERSONAL PROTECTION

Glasses:
Chemical goggles.

Gloves:
PVC chemical resistant type.

Respirator:
Particulate

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Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up all 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.
- Sweep up, shovel up or
- Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).
- Place spilled material in clean, dry, sealable, labelled container.

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.
 - 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.

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Section 7 - HANDLING AND STORAGE

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



+: May be stored together
O: May be stored together with specific precautions
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/m ³	STEL ppm	STEL mg/m ³	Peak ppm	Peak mg/m ³	Max excursion ppm	Max excursion mg/m ³	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								

Source	Material	TWA mg/m ³	Notes
US - Oregon Permissible Exposure Limits (Z3)	sodium chloride (Inert or Nuisance Dust: (d) Total dust)	10	*
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	*

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Source	Material	TWA mg/m ³	Notes
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)	silica amorphous, fumed, crystalline free (Inert or Nuisance Dust: (d) Total dust)	10	*
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	
US - Hawaii Air Contaminant Limits	silica amorphous, fumed, crystalline free (Particulates not other wise regulated - Total dust)	10	
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	*

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Source	Material	TWA mg/m ³	Notes
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

- erythromycin phosphate: CAS:4501- 00- 2

EMERGENCY EXPOSURE LIMITS

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

MATERIAL DATA

EM 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.

ERYTHROMYCIN PHOSPHATE:

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

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evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

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

CEL TWA: 3 mg/m³ (as erythromycin) (compare WEEL-TWA)

A workplace environmental exposure standard (WEEL) is recommended by the AIHA and is based on reported clinical and industrial experience. The limit is thought to prevent possible alterations of the normal bacterial flora in the body or development of immunity to future therapeutic use.

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):

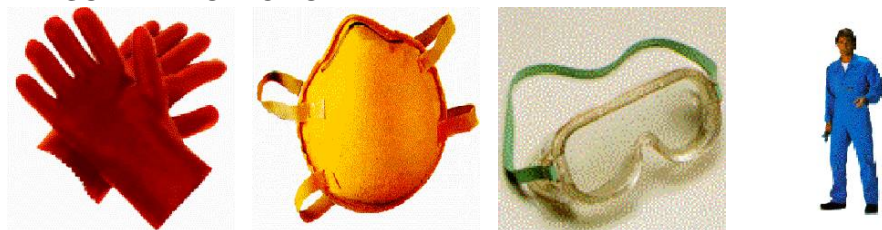
Amorphous crystalline silica shows little potential for producing adverse effects on the lung and exposure standards should reflect a particulate of low intrinsic toxicity. Mixtures of amorphous silicas/ diatomaceous earth and crystalline silica should be monitored as if they comprise only the crystalline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

- polychloroprene
- nitrile rubber

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- butyl rubber
 - fluorocacoutchouc
 - 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.

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.
- Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

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:

direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)

Air Speed:

1- 2.5 m/s (200- 500 f/min.)

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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.)

Within each range the appropriate value depends on:

Lower end of the range

- 1: Room air currents minimal or favourable to capture
- 2: Contaminants of low toxicity or of nuisance value only.
- 3: Intermittent, low production.
- 4: Large hood or large air mass in motion

Upper end of the range

- 1: Disturbing room air currents
- 2: Contaminants of high toxicity
- 3: High production, heavy use
- 4: Small hood- local control only

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

White powder with no 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

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Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

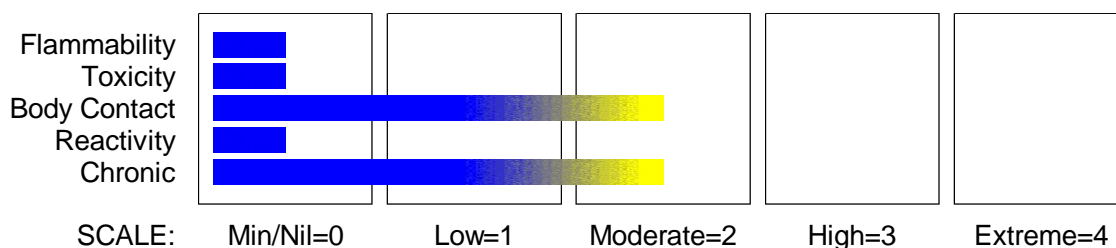
CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

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

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

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

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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.

There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

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) TDL0: 12357 mg/kg/23d
Intravenous (Mouse) LD50: 645 mg/kg
Oral (Human) TDL0: 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

ERYTHROMYCIN PHOSPHATE:

No significant acute toxicological data identified in literature search.

SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:

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

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Section 11 - TOXICOLOGICAL INFORMATION

TOXICITY

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

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 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.

IRRITATION

CARCINOGEN

SILICA	US Environmental Defense Scorecard Recognized Carcinogens	Reference(s)	P65
SILICA	US Environmental Defense Scorecard Suspected Carcinogens	Reference(s)	P65

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Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

SODIUM CHLORIDE:

ERYTHROMYCIN PHOSPHATE:

SILICA AMORPHOUS, FUMED, CRYSTALLINE FREE:

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DO NOT discharge into sewer or waterways.

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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.

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

ERYTHROMYCIN PHOSPHATE:

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

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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

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 [$\text{Si}(\text{OH})_4$]. At pH 9.4 the solubility of amorphous silica is about 120 mg SiO_2/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

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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

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.

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"

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 EM Powder Medication (CW: 4658-75)

No data for erythromycin phosphate (CAS: , 4501-00-2)

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Section 16 - OTHER INFORMATION

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.

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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