

# Esomeprazole Magnesium

sc-207635

Material Safety Data Sheet



The Power to Question

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

### PRODUCT NAME

Esomeprazole Magnesium

### STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

### NFPA



### SUPPLIER

Santa Cruz Biotechnology, Inc.  
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### EMERGENCY

ChemWatch

Within the US & Canada: 877-715-9305

Outside the US & Canada: +800 2436 2255

(1-800-CHEMCALL) or call +613 9573 3112

### SYNONYMS

C34H36MgN6O6S2, "esomeprazole magnesium [CAS RN: 161973-10-0]", "bis(5-methoxy-2-((S)-((4-methoxy-3, 5-dimethyl-2-pyridinyl)methyl)sulfinyl)-, "1H-benzimidazole-1-yl)magnesium trihydrate", "1H-benzimidazole, 5-methoxy-2-(((4-methoxy-3, 5-dimethyl-2-pyridinyl)-", "methyl)sulfinyl-, magnesium trihydrate", "5-methoxy-2-(((4-methoxy-3, 5-dimethyl-2-pyridinyl)methyl)sulfinyl)-", "benzimidazole magnesium trihydrate", "S-omeprazole derivative", "Prilosec isomer derivative", "Nexium tablets/ capsules", "Gastro-oesophageal esophageal reflux disease (GERD) agent", "gastric acid secretion inhibitor", "gastrointestinal agent/ gastric proton-pump inhibitor", anti-ulcerative

## Section 2 - HAZARDS IDENTIFICATION

### CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability:	1	
Toxicity:	2	
Body Contact:	0	
Reactivity:	1	
Chronic:	2	

Min/Nil=0  
Low=1  
Moderate=2  
High=3  
Extreme=4



### CANADIAN WHMIS SYMBOLS



## EMERGENCY OVERVIEW

### RISK

May cause SENSITISATION by skin contact.

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

## POTENTIAL HEALTH EFFECTS

### ACUTE HEALTH EFFECTS

#### SWALLOWED

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

■ Treatment with omeprazole is generally well tolerated.

Side-effects may include headache, diarrhoea, abdominal pain, nausea, URI, dizziness, vomiting, rash, constipation, cough, asthenia and back pain.

■ Gastric proton pump inhibitors (GPPIs) are generally well tolerated, and the incidence of short-term adverse effects is relatively uncommon.

The range and occurrence of adverse effects are similar for all of the proton pump inhibitors, though they have been reported more frequently with omeprazole.

■ Ingestion of esomeprazole magnesium may produce nausea, abdominal pain, vomiting, diarrhoea and headache.

#### EYE

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).

Slight abrasive damage may also result.

#### SKIN

■ The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models).

Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

■ Open cuts, abraded or irritated skin should not be exposed to this material.

■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

#### INHALED

■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models).

Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

## CHRONIC HEALTH EFFECTS

■ Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population.

There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Omeprazole is a skin strong sensitizer in animal assays.

Repeated oral doses of omeprazole in animals have produced adverse effects on kidney and the gastrointestinal tract. Short term tests show that the material is unlikely to be a carcinogenic hazard in man.

In two 24-month carcinogenicity studies in rats, omeprazole (given at 4-352 times the human dosage) produced gastric ECL cell carcinoids in a dose-related manner in both male and female rats. ECL cell hyperplasia was present in all treatment groups. A 78-week mouse carcinogenicity study did not show increased tumor occurrence.

Omeprazole was not mutagenic in an in vitro Ames Salmonella typhimurium assay, an in vitro mouse lymphoma cell assay and an in vivo liver DNA damage assay. A mouse micronucleus test at 625 and 6250 times the human dose gave a borderline result, as did an in vivo bone marrow chromosome aberration test.

In developmental studies with rabbits (at 17-172 times the human dose) the drug produced dose-related increases in embryo-lethality, foetal resorptions, and pregnancy disruptions. In rats, dose-related embryo/foetal toxicity and post-natal developmental toxicity was seen in offspring of parents treated with 13-138 times the human dose.

Sporadic reports have been received of congenital abnormalities occurring in infants born to women receiving the drug during pregnancy.

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.

In a study of 135,000 people 50 or older, those taking high doses of GPPIs for longer than one year have been found to be 2.6 times more likely to break a hip. Those taking smaller doses for 1 to 4 years were 1.2 to 1.6 times more likely to break a hip. The risk of a fracture increased with the length of time taking GPPIs. Theories as to the cause of the increase are the possibility that the reduction of stomach acid reduces the amount of calcium dissolved in the stomach or that GPPIs may interfere with the breakdown and rebuilding of bone by interfering with the acid production of osteoclasts. Also, the reduction of vitamin B12 (by raising homocysteine) may increase bone fragility, an effect that may be offset by the consumption, or by the co-packaging, of about 100 mcg of B12 with the GPPI.

The use of gastric proton pump inhibitors (antiulceratives) has been associated with the induction of carcinoid-like tumours of the gastric mucosa. This is thought to be associated with a complete block of gastric acid secretion leading to hypergastrinaemia and hyperplasia of

enterochromaffin-like cells. As a result, the therapeutic use of these inhibitors is generally restricted.

A number of benzimidazoles have been shown to also inhibit mammalian tubulin polymerisation and to be aneugenic in vivo. Aneugens affect cell division and the mitotic spindle apparatus resulting in loss or gain of whole chromosomes, thereby inducing an "aneuploidy". Mitotic aneuploidy is a characteristic of many types of tumorigenesis (in cancer). Several benzimidazoles have been shown to be genotoxic. Genotoxicity may arise as aneugens may also be clastogens, or may produce clastogenic metabolites. Clastogens increase the rate of genetic mutation by interfering with the function of nucleic acids. A clastogen is a specific mutagen that causes breaks in chromosomes.

### Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
esomeprazole magnesium trihydrate	217087-09-7	>98
a isomer of		
<a href="#">omeprazole</a>	73590-58-6	

### Section 4 - FIRST AID MEASURES

#### SWALLOWED

· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

#### EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

#### SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

#### INHALED

· If dust is inhaled, remove from contaminated area. · Encourage patient to blow nose to ensure clear passage of breathing. · If irritation or discomfort persists seek medical attention.

#### NOTES TO PHYSICIAN

■ Treat symptomatically.

No antidote is known. Omeprazole is extensively protein-bound and is therefore not readily dialysable.

### Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

#### EXTINGUISHING MEDIA

· Foam.  
· Dry chemical powder.

#### FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.  
· Wear breathing apparatus plus protective gloves.

#### GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.  
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.  
Combustion products include: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), sulfur oxides (SO<sub>x</sub>), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

#### FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

#### PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

Respirator:

Particulate

## Section 6 - ACCIDENTAL RELEASE MEASURES

### MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

### MAJOR SPILLS

- Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.

## Section 7 - HANDLING AND STORAGE

### PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
  - Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
  - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

### RECOMMENDED STORAGE METHODS

- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

### STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.

Store below 40 deg. C

## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

The following materials had no OELs on our records

- esomeprazole magnesium trihydrate: CAS:217087-09-7 CAS:161973-10-0
- omeprazole: CAS:73590-58-6

### PERSONAL PROTECTION



### RESPIRATOR

Particulate

Consult your EHS staff for recommendations

### EYE

- When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

### HANDS/FEET

- NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other

protective equipment, to avoid all possible skin contact.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

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

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

#### OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

#### ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

### PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	713.12
Melting Range (°F)	Not available	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°F)	Not available.	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

### APPEARANCE

White to slightly coloured crystalline powder; does not mix well with water. Rapidly degrades in acidic media but is stable under alkaline conditions. At pH 6.8 (buffered), the half-life of the magnesium salt is about 19 hours and about 8 hours at 37 C. Esomeprazole is the S-isomer of omeprazole (Prilosec) (which is a mixture of S- and R-isomers).

Omeprazole hydrolyses readily in acid pH, and rapidly undergoes photodegradation (complete in 3 hours). Omeprazole is not readily biodegradable. The log Kow=2.38.

Material	Value
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## Section 10 - CHEMICAL STABILITY

## CONDITIONS CONTRIBUTING TO INSTABILITY

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

## STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.

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

## Section 11 - TOXICOLOGICAL INFORMATION

esomeprazole magnesium trihydrate

### TOXICITY AND IRRITATION

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

- Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's edema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type.

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE:

TOXICITY IRRITATION

Oral (rat) LD50: >1900 mg/kg (male) \* Eye: Irritant

### TOXICITY

### IRRITATION

#### OMEPRAZOLE:

Oral (rat) LD50: 2210 mg/kg

Nil  
Reported

Intraperitoneal (rat) LD50: 100 mg/kg

Subcutaneous (rat) LD50: >100 mg/kg

Intravenous (rat) LD50: 50 mg/kg

Oral (mouse) LD50: >4000 mg/kg

Intraperitoneal (mouse) LD50: 100 mg/kg

Subcutaneous (mouse) LD50: >100 mg/kg

Intravenous (mouse) LD50: 82.8 mg/kg

■ 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.

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.

Recordings from specific areas of the CNS, hepatitis, jaundice, changes in

urine composition, changes in kidney tubules, normocytic anaemia, body

temperature increase, pleural effusion, cough, urticaria, allergic

rinitis, serum sickness, eosinophilia, interstitial nephritis, dermatitis

after systemic exposure, joint abnormalities, effects on inflammation,

ptosis, changes in motor activity, respiratory depression, diarrhoea,

dyspnea, convulsions, ataxia, body temperature decrease, maternal effects

recorded.

## Section 12 - ECOLOGICAL INFORMATION

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

### Ecotoxicity

Ingredient  
omeprazole

Persistence: Water/Soil Persistence: Air  
HIGH

Bioaccumulation  
LOW

Mobility  
LOW

## Section 13 - DISPOSAL CONSIDERATIONS

### Disposal Instructions

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

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

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

## Section 14 - TRANSPORTATION INFORMATION

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

## Section 15 - REGULATORY INFORMATION

### Regulations for ingredients

**omeprazole (CAS: 73590-58-6) is found on the following regulatory lists;**

"Canada National Pollutant Release Inventory (NPRI)"

**No data for esomeprazole magnesium trihydrate (CAS: , 217087-09-7, 161973-10-0)**

## Section 16 - OTHER INFORMATION

### Ingredients with multiple CAS Nos

Ingredient Name CAS esomeprazole magnesium trihydrate 217087-09-7, 161973-10-0

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■ 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](http://www.chemwatch.net/references).

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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