

Procter&Gamble

MATERIAL SAFETY DATA SHEET

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MSDS Identifier

Prilosec OTC™ Tablets

SECTION I – CHEMICAL / PRODUCT AND COMPANY IDENTIFICATION

THE PROCTER & GAMBLE COMPANY Health Care Research Center 8700 Mason-Montgomery Road Mason, OH 45040-9462		RATING KEY 4=EXTREME 3=HIGH 2=MODERATE 1=SLIGHT	Hazard Rating Health: 1 Flammability: 1 Reactivity: 0
EMERGENCY PHONE:	Transportation Emergency (24 hour) Telephone Number: CHEMTREC: 1-800-424-9300 in the U.S. and Canada; 1-703-527-3887 for calls originating elsewhere or call the Poison Control Center		Prepared by: Jill Karner, CIH Issue Date: December 17, 2007 Last Reviewed: 09/09/2003
Material Name:	Prilosec OTC™ Tablets		

SECTION II – COMPOSITION AND INGREDIENTS

Hazardous ingredients as defined by OSHA, 29 CFR 1910.1200, and/or WHMIS under the HPA. These substances are listed because in their pure bulk form, they meet the OSHA definition of hazardous. Any hazards associated with this finished product are listed in Section III of this MSDS.			
Principal Hazardous Components:	CAS Number	Conc. %	Exposure Limit/ LC50/LD50
Omeprazole magnesium	95382-33-5	3 – 7	0.5 mg/m3 (Internal Exposure Guideline)

SECTION III – HAZARDS IDENTIFICATION

Emergency Overview: As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low. When bulk unpackaged product is handled, there may be a risk. Please refer to the information in this Material Data Safety Sheet. This mixture is a product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the labeled directions.	
Eye:	May cause eye irritation. May cause conjunctivitis.
Skin:	By analogy with a similar substance this material is likely to be a skin sensitizer. May cause sensitization by skin contact.
Inhalation:	Dust may be irritant to the respiratory tract. Higher concentrations may cause nausea and vomiting.
Ingestion:	Adverse effects similar to inhalation may occur. Oral Median Lethal Dose (rat) > 2,000 mg/kg

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SECTION IV – FIRST AID MEASURES

Eye:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. Obtain medical attention.
Skin:	Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur, obtain medical attention.
Inhalation:	Remove patient from exposure. Obtain medical attention if ill effects occur.
Ingestion:	Wash out mouth with water and give 200-300 mls of water to drink. Obtain medical attention if ill effects occur.
Additional First Aid Measures: Note to Physician: Symptomatic treatment and supportive therapy as indicated. For further detail, consult the prescribing information.	

SECTION V – FIRE FIGHTING MEASURES

Flash Point:	Not applicable	Flash Point test method:	Not applicable
Auto-ignition Temperature:	<input checked="" type="checkbox"/> Not applicable <input type="checkbox"/> Not available <input type="checkbox"/> deg. C <input type="checkbox"/> deg. F.	Flammable Limits (% by volume in air)	LEL % N/A UEL % N/A
Extinguishing Media:	Use water spray, alcohol foam, or carbon dioxide.		
Explosion Hazards:	Combustible dust if not in tablet form.		
Special Instructions:	This product may form flammable dust clouds in the air, if dust from tablets is allowed to accumulate and if it is dispersed.		

SECTION VI – ACCIDENTAL RELEASE MEASURES

Personal Safeguards:	Ensure suitable personal protection during removal of spillages. Ensure adequate ventilation.
Environmental Precautions:	Dispose in accordance with all regulations.
Spill Clean-up Procedures:	<i>Household:</i> Safe to dispose of in refuse. <i>Industrial Setting:</i> Ensure suitable personal protection during removal of spillages. Ensure adequate ventilation. In case of accident, avoid breathing dust from crushed tablets. Transfer spilled tablets to a suitable container for disposal. Wash the spillage with water.

SECTION VII – HANDLING AND STORAGE

Recommended Storage Temperature:	Store at room temperature.
Personal Precautions for Safe Storage and Handling:	No special precautions are necessary when handling packed product. The handling of unpackaged product may require precautions. Avoid contact with skin and eyes. Atmospheric levels should be controlled in compliance with the occupational exposure limit. Follow procedures specified in the National Fire Protection Associated Codes and Standards for handling combustible dusts (or explosive dusts).
Conditions for Safe Storage:	Keep container tightly closed. Keep out of reach of children.
Other Precautions:	None

SECTION VIII – EXPOSURE CONTROLS, PERSONAL PROTECTION

This section only applies to the product when used in an <u>industrial setting</u> .	
Ventilation:	Local exhaust ventilation may be needed for control.
Eye Protection:	Chemical tight goggles
Respiratory Protection:	If needed, use a NIOSH approved respirator when there is a potential to be above the safe exposure limit. For bulk handling of this material NIOSH approved air supplied respirator with hoods are recommended.
Skin Protection:	Impervious gloves and apron.
Other Special Protection:	Eyewash station and safety shower in work area.

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SECTION IX – PHYSICAL AND CHEMICAL PROPERTIES

Appearance / Color:	Pink tablet	Melting Point:	Not available
Odor:	Not available	Boiling Point:	Not available
Odor Threshold:	Not available	Solubility in Water:	Not available
Physical State:	Solid	Vapor Pressure (mm Hg):	Not applicable
Vapor Density:	Not applicable	Specific Gravity (H ₂ O=1):	Not applicable
pH:	Not available	Other Data:	Product complies with State and Federal regulations for VOC content.

SECTION X – STABILITY AND REACTIVITY

Stability:	Stable
Possibility of Hazardous Reaction:	Hazardous polymerization will not occur.
Incompatibility: (Materials to avoid)	None known
Hazardous Decomposition Products:	None known

SECTION XI – TOXICOLOGICAL INFORMATION

Chronic Effects:	Ingestion studies in animals have shown that repeated doses produce adverse effects on the kidney and gastrointestinal tract.
Target Organs:	Ingestion studies in animals have shown that repeated doses produce adverse effects on the kidney and gastrointestinal tract.
Carcinogenicity:	Short term tests have shown that it is unlikely to be a carcinogenic hazard to man.
NTP:	No
IARC:	No

SECTION XII – ECOLOGICAL INFORMATION

Relevant ecotoxicity and fate data for ingredients in this formulation have been reviewed. Under normal and foreseeable consumer uses, there are no concerns for aquatic organisms exposed to product ingredients at the anticipated environmental concentrations. The product is compatible with down-the-drain disposal routes, including municipal wastewater treatment processes and septic tank systems. This product is intended for dispersive use and should not be disposed of directly into the environment.

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SECTION XIII – DISPOSAL CONSIDERATIONS

Waste Disposal Method: Disposal is to be performed in compliance with Federal, State/Provincial and Local regulations.

SECTION XIV – TRANSPORTATION

Agency	Classification
US DOT (transportation by ground)	Non-Regulated
IMDG (transportation by sea)	Non-Regulated
IATA (transportation by air)	Non-Regulated

SECTION XV – ADDITIONAL REGULATORY INFORMATION

The product(s) described in this Material Safety Data Sheet are regulated under the Federal Food, Drug and Cosmetics Act and are safe to use as per directions on container, box or accompanying literature (where applicable).

US Federal:

TSCA – All intentionally-added components of this product are listed on the US TSCA Inventory.

SARA 313/302/304/311/312 chemicals: None

US States:

California: This product has been evaluated and does not require warning labeling under California Proposition 65.

California Registration Number: None

State Right-to-Know and CERCLA: The following ingredients present in the finished product are listed on state right-to-know lists or state work exposure lists.

Ingredient(s)	CERCLA RQ	State(s)
Not applicable	Not applicable	Not applicable

SECTION XVI – OTHER INFORMATION

DISCLAIMER: This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered by Procter & Gamble to be dependable and is accurate to the best of the Company's knowledge. It is not meant to be an all-inclusive document on worldwide hazard communication regulations.

This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate protective mechanisms to prevent employee exposures, property damage or release to the environment. Procter & Gamble assumes no responsibility for injury to the recipient or third persons, or for any damage to any property resulting from misuse of the product.