

SAFETY DATA SHEETS

This SDS packet was issued with item:

078464761

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078344652 078344660 078344678 078389542 078464779 078464787

Merial

GASTROGARD(R)

PRODUCT NUMBER(S): 36611

SECTION I CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

IDENTITY (As Used on Label and List):
 TRUE NAME: Omeprazole
 TRADE NAME: GASTROGARD(R)
 PRODUCT NUMBER(S): 36611
 MANUFACTURER'S NAME AND ADDRESS: MERIAL, LIMITED
 2100 RONSON ROAD
 ISELIN, NEW JERSEY 08830-3077
 EMERGENCY TELEPHONE NUMBER: CHEMTREC 1-800-424-9300
 TELEPHONE NUMBER FOR INFORMATION: 1-888-MERIAL 1
 (1-888-637-4251), Option 5
 DATE PREPARED: 01 October 1998
 SIGNATURE OF PREPARER (optional):

SECTION II - COMPOSITION, INFORMATION ON INGREDIENTS

COMPOSITION:

Hazardous Components
 (Specific Chemical

Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	%
Omeprazole	Not Est.	Not Est.	Merck ECL 0.5 mg/m3	37
CAS Number: 73590-58-6				
Non-Hazardous Inert Ingredients	N/A	N/A	N/A	63

SECTION III - HAZARDS IDENTIFICATION

APPEARANCE AND ODOR: Smooth yellow to yellow-tan paste.
 No odor noted.

OSHA/DOT HAZARD CLASSIFICATION(S): Not Applicable

POTENTIAL HEALTH HAZARDS:

INHALATION: Unlikely with normal use

INHALATION LD50: N/A

INGESTION (Rat):

ORAL LD50: 1,520 mg/kg

EYE: Direct Contact May Cause Irritation

SKIN: Unlikely with Normal Use

DERMAL LD50:

SECTION IV - FIRST AID MEASURES

SIGNS AND SYMPTOMS OF EXPOSURE:

EYE: Direct contact with the eye can cause irritation.

SKIN: Omeprazole is slightly irritating to the skin.

INHALATION: Not an expected route of exposure for this product.

INGESTION: Omeprazole is non-toxic orally, might cause diarrhea, headache, drowsiness, or rapid heart rate.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: None Known

EMERGENCY AND FIRST AID PROCEDURES:

EYE: Immediately flush with water for at least 15 minutes, get medical attention if irritation occurs.

SKIN: Immediately flush with soap and water, remove all contaminated clothing. Get medical attention if symptoms occur. Thoroughly clean all contaminated clothing before reuse.

INHALATION: No emergency procedures required.

INGESTION: Get medical symptoms occur. DO NOT induce vomiting unless directed by medical personnel.

NOTE TO PHYSICIAN: Omeprazole is a gastric acid secretion inhibitor which degrades in acid environments such as the stomach.

SECTION V - FIRE FIGHTING MEASURES

FLASH POINT (deg C/deg F) (Method Used): Not Applicable

FLAMMABLE LIMITS: Not Applicable

LEL:

UEL:

EXTINGUISHING MEDIA: Use water spray, dry chemical, CO2, halon, or foam.

SPECIAL FIRE FIGHTING PROCEDURES: Firefighters should wear self-contained breathing apparatus and full turnout suits.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None Known

SECTION VI - ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

For Transportation Related and Large Spills Call CHEMTREC 1-800-424-9300 For small spills, scoop-up all spilled material and place in a sealed, liquid proof container for disposal in accordance with Section XIII. Avoid contact of spilled material with soils to prevent runoff to surface waterways.

SECTION VII - HANDLING AND STORAGE

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING: Avoid contact with eyes and skin. No eating, drinking, or smoking while using this product. Wash thoroughly after use. Store at room temperature, 15 - 30 deg C/ 59 -86 deg F.

OTHER PRECAUTIONS: Keep this and all drugs out of the reach of children.

SECTION VIII - EXPOSURE CONTROLS, PERSONAL PROTECTION

RESPIRATORY PROTECTION (Specify Type): Not necessary

VENTILATION: Not Necessary for this product

LOCAL EXHAUST:

MECHANICAL (General):

SPECIAL:

OTHER:

PROTECTIVE GLOVES: Latex or other impervious gloves

EYE PROTECTION: Safety glasses or goggles

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: No special requirements.

WORK/HYGIENIC PRACTICES: No eating, drinking, or smoking while using this product. Wash thoroughly after using.

SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

FLASH POINT (deg C/deg F) (Method Used): Not applicable

FLAMMABLE LIMITS: Not applicable

LEL:

UEL:

APPEARANCE: Smooth yellow to yellow-tan paste.

BOILING POINT (deg C/deg F): Not Applicable

SPECIFIC GRAVITY (H2O = 1): Not Applicable

pH: Neutral

ODOR: None Noted

VAPOR PRESSURE (mm Hg.): Not Available

FREEZING/MELTING POINT (specify) (deg C/deg F): Not Available

PHYSICAL STATE: Paste

VAPOR DENSITY (AIR = 1): Not Applicable

EVAPORATION RATE (Butyl Acetate = 1): Not Available

SOLUBILITY IN WATER: Insoluble

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GASTROGARD(R)

SECTION X - STABILITY AND REACTIVITY DATA

STABILITY: Stable
CONDITIONS TO AVOID:
INCOMPATIBILITY (Materials to Avoid): None Known
HAZARDOUS DECOMPOSITION OR BYPRODUCTS: Exposure to fire will produce toxic gases including but not limited to SO₂, NO_x, CO, CO₂, formaldehyde, formic acid, and other complex decomposition products in smoke.
HAZARDOUS POLYMERIZATION: Will Not Occur
CONDITIONS TO AVOID:

SECTION XI - TOXICOLOGICAL INFORMATION

ACUTE DATA:
INHALATION: Unlikely with normal use
INHALATION LD50: N/A
INGESTION (Rat):
ORAL LD50: 1,520 mg/kg
EYE: Direct Contact May Cause Irritation
SKIN: Unlikely with Normal Use
DERMAL LD50:
TARGET ORGANS: None Know
CARCINOGENICITY:
NTP? Not Listed
IARC MONOGRAPHS? Not Listed
OSHA REGULATED? Not Listed
SPECIAL STUDIES (epidemiology, carcinogenicity, other studies relevant to subject materials): None

SECTION XII - ECOLOGICAL INFORMATION

ECOTOXICITY (fish and invertebrates, plant life, birds, other):
OMEPRAZOLE:
LC50 (48 hours) FOR DAPHNIA MAGNA: 88.00 ppm. Harmful to aquatic organisms.
ENVIRONMENTAL FATE (persistence, degradation, hydrolytic/photolytic stability, etc.): Omeprazole is only slightly soluble in water (1.3 mg/mL), hydrolyzes readily in acid pH, and rapidly undergoes photodegradation (complete in 3 hours). Omeprazole is not biodegradable. The log Kow = 2.38.

SECTION XIII - DISPOSAL CONSIDERATIONS

RESPONSIBILITY FOR PROPER WASTE DISPOSAL IS WITH THE OWNER OF THE WASTE.
EPA/RCRA WASTE NUMBERS UNDER RCRA 40CFR 261: Not Regulated
WASTE DISPOSAL METHOD: Incinerate in EPA approved facility.
SPECIAL INSTRUCTION OR SPECIFIC LIMITATIONS: Minimized contact of spilled materials with soil and surface waterways.

SECTION XIV - TRANSPORT INFORMATION

	GROUND	DOMESTIC AIR	INT'L AIR	OCEAN
TRANSPORTATION				
SHIPPING NAME	NOT	REGULATED		
UN/ID NO.				
CLASS				
PACKING GRP				
LABELS				
MARKING				
PACKAGING INST				
DOCUMENTATION				
REFERENCE	49CFR	49CFR	IATA	IMDG

SECTION XV - REGULATORY INFORMATION

OSHA: 29 CFR 1910.1200
DOT/IATA/IMDG: Not Regulated
EPA/RCRA: Not Regulated
FREIGHT CLASSIFICATION: Drugs or medicines, NOI, Class 70
NMFC 60000 RVNX

SECTION XVI - OTHER

RIGHT TO KNOW HAZARD INFORMATION: (4=Severe Hazard;
3=Serious Hazard; 2=Moderate Hazard; 1=Slight Hazard;
0=Minimal Hazard)

HEALTH: 0
FIRE: 0
REACTIVITY: 0
OTHER (Specify): 0

KEY/LEGENDS USED: "N/A" = Not Applicable; "Not Est." = Not Established

PREPARATION DATE: 01 October 1998

REVISION INFORMATION: Initial Version

OTHER:

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COMPAS Code: 40440010