



## Material Safety Data Sheet

ISO/DIS 11014 / 29 CFR 1910.1200 / ANSI Z400.1

Printing date 12/11/2004

Reviewed on 12/11/2004

### 1 Identification of substance

- **Product details**
- **Trade name:** ULCERGARD
- **Manufacturer/Supplier:**  
Merial Limited  
3239 Satellite Blvd.  
Duluth, Ga. 30096-4640  
1-888-MERIAL 1 (1-888-637-4251)
- **Emergency information:**  
**Spill Information:**  
CHEMTREC® 1-800-424-9300  
CHEMTREC® International 1+703-527-3887  
International calls 011+703-527-3887  
Reverse charges.

### 2 Composition/Data on components

- **Chemical characterization**

- **Components:**

	Non hazardous inert ingredients	63.0 %
73590-58-6	Omeprazole	37.0%

### 3 Hazards identification

- **Hazard description:** Not applicable.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and from company and regulatory data.
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

### 4 First aid measures

- **General information:** No special measures required.
- **After inhalation:** Not an expected route of entry.

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- **After skin contact:**  
Immediately wash with water and soap and rinse thoroughly.  
Persons developing a reaction after contact with the product should avoid handling the product in future.
- **After eye contact:**  
Rinse opened eye for a minimum of 15 minutes under running water. Get medical attention immediately.
- **After swallowing:** Do not induce vomiting; immediately call for medical help.
- **After self injection** Not an expected route of entry.
- **Information for doctor.**  
**The following symptoms may occur**  
Direct contact with the eye can cause irritation. Omeprazole is slightly irritating to the skin. Omeprazole is non-toxic orally, but might cause diarrhea, headache, drowsiness or rapid heart rate.

### 5 Fire fighting measures

- **Suitable extinguishing agents:** Use water spray or all purpose dry chemical.
- **Protective equipment:**  
Fire fighters should wear self-contained breathing apparatus and full protective equipment.

### 6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:**  
Do not allow product to reach sewage system or any water course.
- **Measures for cleaning/collecting:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose of contaminated material as waste according to section XIII.
- **Additional information:** No dangerous substances are released.

### 7 Handling and storage

- **Handling:**
- **Information for safe handling:**  
Store in cool, dry place in tightly closed containers.  
Handle with care. Avoid jolting and impact.  
Replace cap after use.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original container.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in a cool, dry, well ventilated place.
- **Recommended storage temperature:** 15°C-30°C

### 8 Exposure controls and personal protection

- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
 Wash hands before breaks and at the end of work.  
 Avoid contact with the eyes and skin.  
 Do not eat, drink, smoke or inhale.  
 Do not store food in the working area.
- **Breathing equipment:** Not required for this formulation when used in accordance with directions.
- **Protection of hands:** Impervious gloves to minimize skin contact.
- **Penetration time of glove material**  
 The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required under normal conditions of use.

### 9 Physical and chemical properties

#### · General Information

<b>Form:</b>	Paste
<b>Color:</b>	Yellow-brown
<b>Odor:</b>	Slight or no odor

#### · Change in condition

**Melting point/Melting range:** Undetermined.  
**Boiling point/Boiling range:** Undetermined.

· **Flash point:** Not applicable.

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Specific gravity:** Not determined.

#### · Solubility in / Miscibility with

**Water:** Insoluble in water.

#### · Solvent content:

**Organic solvents:** 0.0 %

### 10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**  
 No decomposition if used according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous products of decomposition:**  
 Sulfur oxides (SO<sub>x</sub>)  
 Nitrogen oxides  
 Carbon monoxide and carbon dioxide  
 Formaldehyde

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Formic acid  
Other complex byproducts in smoke

### 11 Toxicological information

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

**73590-58-6 Omeprazole**

Oral	LD50	1520 mg/kg (mouse)
		3320 mg/kg (rat)

· **Primary irritant effect:**

- **on the skin:** No irritating effect known.
- **on the eye:** No irritating effect known.
- **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

### 12 Ecological information

· **Ecotoxicological effects:**

· **Acquatic toxicity:**

**73590-58-6 Omeprazole**

LC50 / 48 hrs	.088 ppb (Daphnia magna)
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· **Remark:**

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

- **General notes:** Not known to be hazardous to water.

### 13 Disposal considerations

· **Product:**

- **Recommendation:** Disposal must be made according to official regulations.

· **Uncleaned packagings:**

- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

· **DOT regulations:**

- **Hazard class:** -

· **Land transport ADR/RID (cross-border):**

- **ADR/RID class:** -

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**· Maritime transport IMDG:**

**· IMDG Class:** -

**· Marine pollutant:** No

**· Air transport ICAO-TI and IATA-DGR:**

**· ICAO/IATA Class:** -

### 15 Regulations

**· Sara**

**· Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

**· Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

**· TSCA (Toxic Substances Control Act):**

None of the ingredients are listed.

**· CA Proposition 65**

**· Chemicals known to cause cancer:**

None of the ingredients are listed.

**· Chemicals known to cause reproductive toxicity:**

None of the ingredients are listed.

**· Carcinogenesis potential categories**

**· EPA (Environmental Protection Agency)**

None of the ingredients is listed.

**· IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

**· NTP (National Toxicology Program)**

None of the ingredients is listed.

**· TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

**· MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

**· NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

**· OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**· Product related hazard informations:**

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

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**· Safety phrases:**

29/56 Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point

**16 Other information**

**· Contact:** MSDS Coordinator, [msds@merial.com](mailto:msds@merial.com)

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