

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078801141

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

078438921 078800752 078800760 078800778 078801125 078801133 078937557

## Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

#### 1 Identification

- **Product identifier**
- **Trade name:** ULCERGARD
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Merial, Inc.  
3239 Satellite Blvd.  
Duluth, Ga. 30096-4640  
1-888-MERIAL 1 (1-888-637-4251)
- **Emergency telephone number:**  
Spill Information:  
CHEMTREC® 1-800-424-9300  
CHEMTREC® International 1+703-527-3887  
International calls 011+703-527-3887  
Reverse charges.

#### 2 Hazard(s) identification

- **Classification of the substance or mixture**  
The product is not classified according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



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

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

#### 3 Composition/information on ingredients

- **Chemical characterization:** Mixtures

- **Components:**

	Non hazardous inert ingredients	63.0%
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# Safety Data Sheet


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

Printing date 09/19/2016

Reviewed on 07/28/2016

Trade name: **ULCERGARD**

73590-58-6 Omeprazole

 Acute Tox. 4, H302

37.0%

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Not an expected route of entry.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **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**
- **Most important symptoms and effects, both acute and delayed**  
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.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use water spray or all purpose dry chemical.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**  
Fire fighters should wear self-contained breathing apparatus and full protective equipment.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose of contaminated material as waste according to section 13.
- **Reference to other sections** No dangerous substances are released.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Store in cool, dry place in tightly closed containers.  
Handle with care. Avoid jolting and impact.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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

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# Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

Trade name: **ULCERGARD**· **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Control parameters**
- **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.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **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 through 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

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

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

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	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.
- **Organic solvents:** 0.0 %
- **Other information** No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.

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# Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

**Trade name: ULCERGARD**

- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
  - Sulfur oxides (SO<sub>x</sub>)
  - Nitrogen oxides
  - Carbon monoxide and carbon dioxide
  - Formaldehyde
  - Formic acid
  - Other complex byproducts in smoke

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· <b>LD/LC50 values that are relevant for classification:</b>		
<b>73590-58-6 Omeprazole</b>		
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.

- **Carcinogenic categories**

· <b>IARC (International Agency for Research on Cancer)</b>
None of the ingredients is listed.

· <b>NTP (National Toxicology Program)</b>
None of the ingredients is listed.

· <b>OSHA-Ca (Occupational Safety &amp; Health Administration)</b>
None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**

· <b>Aquatic toxicity:</b>
<b>73590-58-6 Omeprazole</b>
LC50 / 48 hrs
.088 ppb (Daphnia magna)

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

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# Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

**Trade name: ULCERGARD**

- **Ecotoxological effects:**
- **Remark:**  
Omeprazole hydrolyzes readily in acid pH, and rapidly undergoes photodegradation (complete in 3 hours).  
Omeprazole is not biodegradable. The log Kow=2.38.
- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Can be disposed of with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.  
Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>UN proper shipping name</b>   |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>   | Void            |
| · <b>Packing group</b>   |                 |
| · <b>DOT, ADR, IMDG, IATA</b>  | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | Void            |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA**

· <b>Section 355 (extremely hazardous substances):</b>
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None of the ingredients are listed.
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# Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

**Trade name: ULCERGARD****· 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 for females:**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

**· Carcinogenesis potential categories****· EPA (Environmental Protection Agency)**

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.

**· GHS label elements** Void**· Hazard pictograms** Void**· Signal word** Void**· Hazard statements** Void**· Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**16 Other information****· Contact:** SDS Coordinator, [msds@merial.com](mailto:msds@merial.com)**· Date of preparation / last revision** 09/19/2016 / -**· Abbreviations and acronyms:**

Acute Tox. 4: Acute toxicity – Category 4

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## Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

### 1 Identification

- **Product identifier**
- **Trade name:** ULCERGARD
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Merial, Inc.  
3239 Satellite Blvd.  
Duluth, Ga. 30096-4640  
1-888-MERIAL 1 (1-888-637-4251)
- **Emergency telephone number:**  
Spill Information:  
CHEMTREC® 1-800-424-9300  
CHEMTREC® International 1+703-527-3887  
International calls 011+703-527-3887  
Reverse charges.

### 2 Hazard(s) identification

- **Classification of the substance or mixture**  
The product is not classified according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



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

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization:** Mixtures

- **Components:**

	Non hazardous inert ingredients	63.0%
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# Safety Data Sheet


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

Printing date 09/19/2016

Reviewed on 07/28/2016

**Trade name: ULCERGARD**

73590-58-6 Omeprazole

 Acute Tox. 4, H302

37.0%

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Not an expected route of entry.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **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**
- **Most important symptoms and effects, both acute and delayed**  
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.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use water spray or all purpose dry chemical.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**  
Fire fighters should wear self-contained breathing apparatus and full protective equipment.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose of contaminated material as waste according to section 13.
- **Reference to other sections** No dangerous substances are released.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Store in cool, dry place in tightly closed containers.  
Handle with care. Avoid jolting and impact.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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

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# Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

Trade name: **ULCERGARD**· **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Control parameters**
- **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.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **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 through 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

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

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

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	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**

<b>Water:</b>	Insoluble in water.
<b>Organic solvents:</b>	0.0 %
- **Other information** No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.

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# Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

**Trade name: ULCERGARD**

- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
  - Sulfur oxides (SO<sub>x</sub>)
  - Nitrogen oxides
  - Carbon monoxide and carbon dioxide
  - Formaldehyde
  - Formic acid
  - Other complex byproducts in smoke

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· <b>LD/LC50 values that are relevant for classification:</b>		
<b>73590-58-6 Omeprazole</b>		
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.

- **Carcinogenic categories**

· <b>IARC (International Agency for Research on Cancer)</b>
None of the ingredients is listed.

· <b>NTP (National Toxicology Program)</b>
None of the ingredients is listed.

· <b>OSHA-Ca (Occupational Safety &amp; Health Administration)</b>
None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**

· <b>Aquatic toxicity:</b>
<b>73590-58-6 Omeprazole</b>
LC50 / 48 hrs
.088 ppb (Daphnia magna)

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

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# Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

**Trade name: ULCERGARD**

- **Ecotoxological effects:**
- **Remark:**  
Omeprazole hydrolyzes readily in acid pH, and rapidly undergoes photodegradation (complete in 3 hours).  
Omeprazole is not biodegradable. The log Kow=2.38.
- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Can be disposed of with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.  
Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>UN proper shipping name</b>   |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>   | Void            |
| · <b>Packing group</b>   |                 |
| · <b>DOT, ADR, IMDG, IATA</b>  | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | Void            |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA**

· <b>Section 355 (extremely hazardous substances):</b>
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None of the ingredients are listed.
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# Safety Data Sheet

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

Printing date 09/19/2016

Reviewed on 07/28/2016

**Trade name: ULCERGARD****· 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 for females:**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

**· Carcinogenesis potential categories****· EPA (Environmental Protection Agency)**

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.

**· GHS label elements** Void**· Hazard pictograms** Void**· Signal word** Void**· Hazard statements** Void**· Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**16 Other information****· Contact:** SDS Coordinator, [msds@merial.com](mailto:msds@merial.com)**· Date of preparation / last revision** 09/19/2016 / -**· Abbreviations and acronyms:**

Acute Tox. 4: Acute toxicity – Category 4

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