

## SAFETY DATA SHEET

Preparation Date: 6/6/2016

Revision date 2/28/2019

Revision Number: G2

### 1. IDENTIFICATION

#### Product identifier

**Product code:** O1405  
**Product Name:** OMEPRAZOLE, USP

#### Other means of identification

**Synonyms:** 5-Methoxy-2-(((4-methoxy-3,5-dimethyl-2-pyridyl)methyl)sulfinyl)benzimidazole  
**CAS #:** 73590-58-6  
**RTECS #** DD9087000  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** Medication.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Tom Tyner (USA - West Coast)  
**Contact Person:** Ibad Tirmiz (USA - East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

#### Label elements

##### Warning

**Hazard statements**  
 Causes skin irritation  
 Causes serious eye irritation  
 May cause respiratory irritation

**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

May be harmful if swallowed

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling

Avoid breathing dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

Wear protective gloves

Wear eye/face protection

**Precautionary Statements - Response**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

**Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS No	Weight-%
Omeprazole	73590-58-6	100

**4. FIRST AID MEASURES****First aid measures****General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.

**Eye Contact:**

Flush eyes with water for 15 minutes. Get medical attention.

**Inhalation:**

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**Ingestion:**

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

### **Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	Causes serious eye irritation Causes skin irritation Irritating to respiratory system May cause abdominal pain, nausea, vomiting, diarrhea May cause constipation Weakness May cause muscle and joint pain Dryness of mouth Sweating and flushing of skin May affect respiration Dyspnea (Shortness of breath and difficulty breathing) Central nervous system effects May cause drowsiness or dizziness Convulsions Ataxia Confusion Headache May affect the cardiovascular system Chest tightness or pain Weak, rapid pulse or rapid heart rate (Tachycardia) Bradycardia Heart palpitations Cardiac arrhythmias May affect the liver It may affect the kidneys
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### **Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

### **Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

## **5. FIRE-FIGHTING MEASURES**

### **Extinguishing Media**

**Suitable Extinguishing Media:** Carbon dioxide (CO<sub>2</sub>). Dry chemical. Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

### **Specific hazards arising from the chemical**

**Hazardous combustion products** Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO<sub>x</sub>). Sulfur oxides.

**Specific hazards** May be combustible at high temperatures.

### **Special Protective Actions for Firefighters**

**Specific Methods:** No information available

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Avoid breathing dust. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Remove all sources of ignition. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

#### **Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Use only in well-ventilated areas. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep refrigerated. Store at 2-8 deg. C. Moisture sensitive. Protect from moisture. Store away from incompatible materials.

#### **Incompatible Materials:**

Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Omeprazole	73590-58-6	None	None	None	None

##### **Canada**

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Omeprazole	73590-58-6	None	None	None	None

##### **Australia and Mexico**

Component	CAS No	Australia	Mexico
Omeprazole	73590-58-6	None	None

### Appropriate engineering controls

**Engineering measures to reduce exposure:** Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

**Eye protection:** Safety glasses with side-shields. or Goggles

**Skin and body protection:** Long sleeved clothing  
Gloves  
Chemical resistant apron

**Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White. Off-white.
<b>Odor:</b> No information available.	<b>Taste</b> No information available.	<b>Formula</b> C17H19N3O3S
<b>Molecular/Formula weight (g/mole):</b> 345.42 g/mol	<b>Flammability (solid, gas)</b> no data available	<b>Flashpoint (°C/°F):</b> No information available
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 156 °C/ 312.8 °F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> 2.23	<b>Viscosity:</b> No information available

**Miscibility:**  
No information available

**Solubility:**  
Freely soluble in Methanol  
Freely soluble in Ethanol  
Very slightly soluble in water

## 10. STABILITY AND REACTIVITY

**Reactivity**  
May react with strong oxidizers

### Chemical stability

**Stability:** Moisture Sensitive. Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Exposure to moisture. Exposure to moist air. Incompatible materials.

**Incompatible Materials:** Strong oxidizing agents

**Hazardous decomposition products:** Carbon oxides. Nitrogen oxides (NOx). Sulfur oxides.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Ingestion. Inhalation.

### Acute Toxicity

### Component Information

Omeprazole	
CAS No	73590-58-6

**LD50/oral/rat** = 2210 mg/kg Oral LD50 Rat  
**LD50/oral/mouse** = >4000 mg/kg  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = No information available

### Product Information

**LD50/oral/rat** =  
**Value - Acute Tox** = 2210 mg/kg

**LD50/oral/mouse** =

**Value - Acute Tox Oral** = >4000 mg/kg

**LD50/dermal/rabbit**

**Value - Acute Tox** = No information available

**LD50/dermal/rat**

**VALUE - Acute Tox Dermal** = No information available

**LC50/inhalation/rat**

**VALUE-Vapor** = No information available

**VALUE-Gas** = No information available

**VALUE-Dust/Mist** = No information available

**LC50/Inhalation/mouse**

**VALUE-Vapor** = No information available

**VALUE - Gas** = No information available

**VALUE - Dust/Mist** = No information available

**Symptoms**

**Skin Contact:** Causes skin irritation.

**Eye Contact:** Causes serious eye irritation.

**Inhalation** Irritating to respiratory system.

**Ingestion** May be harmful if swallowed. May cause gastrointestinal tract irritation with nausea, vomiting. May cause abdominal pain. May cause hypermotility, diarrhea. May cause constipation. May cause flatulence. May cause chest pain. May cause loss of appetite. It may affect the kidneys and liver. May affect behavior/central nervous system (convulsions/seizures). May affect behavior/central nervous system (ataxia). May affect behavior/central nervous system (dizziness, headache). May affect respiration (dyspnea, respiratory depression). May cause drooping of eyelids (ptosis). May cause flushing and sweating. May cause dry mouth. May cause stomatitis. May cause muscle weakness. May cause muscle cramps. May cause joint and muscle pain. May affect behavior/central nervous system (tiredness). May affect behavior/central nervous system (confusion). It may affect behavior/central nervous system (drowsiness). May also cause anxiety and stress. May cause blurred or foggy vision. May affect the cardiovascular system (cardiac arrhythmias). May cause coughing.

**Aspiration hazard** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity** Prolonged or repeated ingestion may affect the liver (hepatitis). Prolonged or repeated ingestion may affect the kidneys. Prolonged or repeated ingestion may cause weight loss. Prolonged or repeated ingestion may cause atrophic gastritis.

**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic	Australia - Prohibited Carcinogenic
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						<b>Substances</b>	<b>Substances</b>
Omeprazole	73590-58-6	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available  
**Developmental Effects:** No information available  
**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** respiratory system.  
**STOT - repeated exposure** No information available.  
**Target Organs:** No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.  
**Persistence and degradability:** No information available  
**Bioaccumulative potential:** No information available.  
**Mobility in soil** No information available  
**Other adverse effects** No information available.

**13. DISPOSAL CONSIDERATIONS**

**Disposal Methods**

**Waste from residues / unused products:**  
Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**  
Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Omeprazole	73590-58-6	None	None	None	None

**14. TRANSPORT INFORMATION**

**DOT**  
**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Class** No information available



<b>Packing group:</b>	No information available
<b>Emergency Response Guide Number</b>	No information available
<b>Marine Pollutant</b>	No data available
<b>DOT RQ (lbs):</b>	No information available
<b>Special Provisions</b>	No Information available
<b>Symbol(s):</b>	No information available
<b>Description:</b>	No information available

**TDG (Canada)**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Marine Pollutant</b>	No Information available
<b>Description:</b>	No information available

**ADR**

<b>UN Number</b>	Not regulated
<b>Proper Shipping Name:</b>	No information available
<b>Transport hazard class(es)</b>	No information available
<b>Packing group</b>	No information available
<b>Subsidiary Risk:</b>	No information available

**IMDG**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Marine Pollutant</b>	No information available

**RID**

<b>UN Number</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Transport hazard class(es)</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing group</b>	No information available

**ICAO (air)**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available

**IATA**

<b>UN Number</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Transport hazard class(es)</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing group</b>	No information available
<b>Precautionary Statements - Response</b>	IF exposed or concerned
<b>Special Provisions</b>	No information available

<b>15. REGULATORY INFORMATION</b>
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## International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
Omeprazole	73590-58-6	Not Listed	Not present	Not present	Not present	Not listed	Not listed	Not present

## U.S. Regulations

### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

#### Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

#### Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Omeprazole	73590-58-6	Not Listed	Not Listed	Not Listed	Not Listed

## CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Omeprazole	73590-58-6	None	None	None	None	None

## U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Omeprazole	73590-58-6	Not Applicable	Not Applicable

## Canada

### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

## DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Omeprazole	73590-58-6	Not Listed	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Omeprazole	73590-58-6	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting

Omeprazole	73590-58-6	Not listed
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## EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Omeprazole	73590-58-6	

EU - CLP (1272/2008)

## R-phrases(s)

R36/37/38 - Irritating to eyes, respiratory system and skin

## S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Omeprazole	73590-58-6		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

## Indication of danger:

Xi - Irritant

Xi



## 16. OTHER INFORMATION

Preparation Date: 6/6/2016  
Revision date: 2/28/2019  
Prepared by: Sonia Owen

## Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet