SAFETY DATA SHEET

1. Identification

Product identifier: Omeprazole
Other means of identification:
   Chemical name: 1H-Benzimidazole, 5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-

Manufacturer/Importer/Supplier/Distributor information

Company name: Total Pharmacy Supply
Address: 3400 Avenue E East
          Arlington
          TX
          76040
          US
Telephone: (800) 878-2822
Website: www.totalpharmacysupply.com

Emergency phone number:
   CHEMTREC within US & Canada: 1-800-424-9300
   CHEMTREC outside US & Canada: +1 703-527-3887

2. Hazard(s) identification

Note: This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Physical hazards: Not classified.
Health hazards:
   Serious eye damage/eye irritation: Category 2B
   Sensitization, skin: Category 1
OSHA hazard(s): Not classified.

Label elements

Signal word: Warning
Hazard statement: May cause an allergic skin reaction. Causes eye irritation.
Precautionary statement:
   Prevention: Wash thoroughly after handling. Avoid breathing dust. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.
   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 or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
   Storage: Not available.
   Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Substance

Material name: Omeprazole
SDS-35TPS Issue date: 06-21-2016
Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omeprazole</td>
<td></td>
<td>73590-58-6</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Irritation of eyes and mucous membranes. May cause allergic skin reaction.

Indication of immediate medical attention and special treatment needed
Treatment of overdose should be symptomatic and supportive. Administer activated charcoal as a slurry. Monitor blood pressure. Monitor fluid and electrolyte status. Monitor cardiac function. Sinus tachydysrhythmias do not need to be routinely treated unless patient is hemodynamically unstable. This material is not dialyzable. (Meditext). (USP DI).

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling
As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omeprazole (CAS 73590-58-6)</td>
<td>TWA</td>
<td>0.05 mg/m³</td>
</tr>
</tbody>
</table>

Biological limit values
No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White to off-white crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

302 - 320 °F (150 - 160 °C) (decomposes)

Initial boiling point and boiling range

1112 °F (600 °C)

Flash point

602.06 °F (316.70 °C)

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

< 0.0000001 kPa at 25 °C

Vapor density

Not available.

Relative density

Not available.

Solubility in water

Very slightly soluble.

Partition coefficient (n-octanol/water)

2.23

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Chemical family

Substituted benzimidazole.

Dust explosion properties

Kst

249 bar.m/s
Minimum ignition energy (MIE) - dust cloud

< 3 mJ

Molecular formula
C17-H19-N3-O3-S

Molecular weight
345.42 g/mol

Potential for dust explosion
May form explosive dust-air mixtures.

Solubility (other)
Soluble in dichloromethane; slightly soluble in acetone and in isopropanol; sparingly soluble in methanol and in alcohol.

Specific gravity
1.37

10. Stability and reactivity

Reactivity
No reactivity hazards known.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None known.

Incompatible materials
Strong oxidizing agents.

Hazardous decomposition products
NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion
Based on available data, the classification criteria are not met.

Inhalation
Due to lack of data the classification is not possible.

Skin contact
May cause an allergic skin reaction.

Eye contact
Causes eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics

Medical conditions aggravated by exposure
Chronic liver disease.

Acute toxicity
Based on available data, the classification criteria are not met.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
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<tr>
<td>Omeprazole (CAS 73590-58-6)</td>
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</tr>
<tr>
<td>Acute</td>
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<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>&gt; 4 g/kg</td>
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<tr>
<td></td>
<td>Rat</td>
<td>2210 mg/kg</td>
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</table>

Skin corrosion/irritation
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation
Causes eye irritation.

Local effects
Irritancy test
Result: Irritant.
Organ: Eye
Severity: Slight.

Irritancy test
Result: Irritant.
Organ: Skin
Severity: Slight.

Respiratory sensitization
Due to lack of data the classification is not possible.

Skin sensitization
May cause an allergic skin reaction.

Sensitization
Maximization test
Result: Sensitization.
Species: Guinea pig
Organ: Skin
Severity: Strong.
Germ cell mutagenicity

Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

**Mutagenicity**

- Ames assay
  - Result: Negative.
- In-vitro cell forward mutation assay in mouse lymphoma cells
  - Result: Negative.
- In-vitro chromosomal aberration assay in human lymphocytes
  - Result: Positive.
- In-vivo DNA damage assay in rat liver
  - Result: Negative.
- In-vivo chromosomal aberration assay in bone marrow cells
  - Result: Positive.
- In-vivo mouse micronucleus test
  - Result: Positive.

**Carcinogenicity**

Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA. Proton pump inhibitors increase serum gastrin, stimulating proliferation of gastric enterochromaffin-like (ECL) cells. Over time this may result in ECL cell hyperplasia in rats and mice and gastric carcinoids in rats. Therapeutic use of PPIs has not been conclusively associated with gastric cancer in humans.

1.7 - 140.8 mg/kg/day Carcinogenicity study
  - Result: A dose-related significant increase in gastric carcinoid tumors and enterochromaffin-like (ECL) cell hyperplasia in both male and female rats.
  - Species: Rat

**Reproductive toxicity**

Based on available data, the classification criteria are not met. Epidemiological studies have not shown an association between the use of proton pump inhibitors during pregnancy and an increased risk of birth defects.

**Reproductivity**

- 13.8 - 138 mg/kg/day Reproductivity study
  - Result: Dose-related embryo/fetal toxicity and postnatal developmental toxicity were observed.
  - Species: Rat
- 138 mg/kg/day Reproductivity study
  - Result: No effect on fertility noticed while given as an oral dose.
  - Species: Rat
- 6.9 - 69.1 mg/kg/day Reproductivity study
  - Result: Dose-related increases in embryo-lethality, fetal resorptions, and pregnancy disruption.
  - Species: Rabbit
- 69 mg/kg/day Reproductivity study
  - Result: No birth defects noticed when given as oral dose.
  - Species: Rabbit

**Specific target organ toxicity - single exposure**

Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure**

Due to lack of data the classification is not possible.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

12. Ecological information

**Ecotoxicity**

- No ecotoxicity data noted for the ingredient(s).

**Persistence and degradability**

- No data is available on the degradability of this product.

**Bioaccumulative potential**

- Not available.

**Mobility in soil**

- Not available.

**Other adverse effects**

- Not available.

13. Disposal considerations

**Disposal instructions**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal regulations**

- Not available.

**Hazardous waste code**

- Not available.

**Waste from residues / unused products**

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information
DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

15. Regulatory information
US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
Not regulated.

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories
Country(s) or region | Inventory name | On inventory (yes/no)*
--- | --- | ---
Australia | Australian Inventory of Chemical Substances (AICS) | No
Canada | Domestic Substances List (DSL) | No
Canada | Non-Domestic Substances List (NDSL) | No
China | Inventory of Existing Chemical Substances in China (IECSC) | No
Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No
Europe | European List of Notified Chemical Substances (ELINCS) | No
Japan | Inventory of Existing and New Chemical Substances (ENCS) | No
Korea | Existing Chemicals List (ECL) | No
New Zealand | New Zealand Inventory | Yes
Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No
United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision
Issue date
06-21-2016