KalChem INTERNATIONAL
Compounding Chemicals You Can Trust

Unit-4

SMILAX LABORATORIES LIMITED

SAFETY DATA SHEET

1. Identification

Product identifier Omeprazole

Other means of identification

CAS number 73590-58-6

Chemical name 1H-Benzimidazole, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-

Recommended use Manufacturing of Finished products

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Smilax Laboratories Limited

Address Unit-4, Plot No:70
JN Pharma city
Parawada
Vishakapatnam-531019
India.

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Serious eye damage/eye irritation — Category 2B

Sensitization, skin — Category 1

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Warning

Hazard statement May cause an allergic skin reaction. Causes eye irritation.

Precautionary statement

Prevention Avoid breathing dust. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.

Response If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. 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.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) 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.

Supplemental information Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Omeprazole		73590-58-6	100

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. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Remove contaminated clothing immediately and wash skin with soap and water.

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
Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically. Treatment of overdose may include: 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.

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

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.

General fire hazards
No unusual fire or explosion hazards noted.

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. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Wear appropriate protective equipment and clothing during clean-up.

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

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

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7. Handling and storage

Precautions for safe handling

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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

This material should be handled and stored per label.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

ACGIH

Material	Type	Value
Omeprazole (CAS 73590-58-6)	TWA	0.05 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

9. Physical and chemical properties

Appearance

White color powder

Physical state

Solid.

Form

Powder.

Color

White. Off-white.

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

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

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(ies)	
Solubility (water)	Very slightly soluble.
Solubility (other)	Acetone: Slightly soluble. Alcohol: Sparingly soluble. Dichloromethane: Soluble. Methanol: Sparingly 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.
Specific gravity	1.37

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
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	
Inhalation	Knowledge about health hazard is incomplete.
Skin contact	May cause an allergic skin reaction.
Eye contact	Causes eye irritation.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics	Proton pump inhibitors: Headache. Gastrointestinal disturbances. Dizziness. Drowsiness. Cough. Chills. Fever. Sore throat. Confusion. Anxiety. Blurred vision. Loss of appetite. Chest pain. Joint pain. Tiredness. Weakness.

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QA
07/02/22

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Omeprazole (CAS 73590-58-6)		
Oral		
LD50	Rat	2210 mg/kg
Acute		
Oral		
LD50	Rat	2210 mg/kg

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

Serious eye damage/eye irritation Causes eye irritation.

Local effects

Eye irritation
Result: Irritant.
Severity: Slight.
Skin irritation
Result: Irritant.
Severity: Slight.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization May cause an allergic skin reaction.

Maximisation test
Result: Sensitization.
Species: Guinea pig
Organ: Skin.
Severity: Strong.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

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

Carcinogenicity Knowledge about carcinogenicity is incomplete. 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 proton pump inhibitors has not been conclusively associated with gastric cancer in humans.

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

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete. 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
Result: Dose-related embryo/fetal toxicity and postnatal developmental toxicity were observed.
Species: Rat
138 mg/kg/day Reproductivity
Result: Negative.
Species: Rat
6.9 - 69.1 mg/kg/day Reproductivity
Result: Dose-related increases in embryo-lethality, fetal resorptions, and pregnancy disruption.
Species: Rabbit
69 mg/kg/day Reproductivity
Result: No adverse effects observed.
Species: Rabbit

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

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

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Octanol/water partition coefficient log Kow
2.23

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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 Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products 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 Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Combustible dust
Serious eye damage or eye irritation
Respiratory or skin sensitization

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) 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.

16. Other information, including date of preparation or last revision

Further information : Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Disclaimer : The information contained herein is applicable solely to the chemical substance and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

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