SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
Product form : Mixture
Product name. : Omeprazole Delayed Release Capsules USP 10, 20, 40mg

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet
Dr. Reddy's Laboratories Ltd.
8-2-337 Road No. 3, Banjara Hills
Hyderabad 500-034, - India
T +91-40-49002900 - F +91-40-49002999

1.4. Emergency telephone number
Emergency number : CHEMTREC (24 hrs., 7 days per week): United States: (800) 424-9300 CCN614136

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
GHS-US classification
Skin Sens. 1 H317

2.2. Label elements
GHS-US labelling
Hazard pictograms (GHS-US) :

Signal word (GHS-US) : Warning
Hazard statements (GHS-US) : H317 - May cause an allergic skin reaction
Precautionary statements (GHS-US) : P261 - Avoid breathing dust
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P321 - Specific treatment (see Section 4 on this label)
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse
P501 - Dispose of contents/container in accordance with local and national regulations

2.3. Other hazards
No additional information available

2.4. Unknown acute toxicity (GHS-US)
No data available

SECTION 3: Composition/information on ingredients

3.1. Substances
Not applicable
Full text of H-phrases: see section 16

3.2. Mixture
Only active ingredients are shown. There are no additional hazardous components present above relevant thresholds in this product. Specific composition withheld as trade secret.
Full text of H-phrases: see section 16

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>GHS-US classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omeprazole (Main constituent)</td>
<td>(CAS No) 73590-58-6</td>
<td>5-10</td>
<td>Acute Tox. 4 (Oral), H302 Skin Sens. 1, H317</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Allow the victim to rest. If inhaled, remove victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

First-aid measures after eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. If symptoms persist, contact a doctor or physician.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after skin contact: May cause an allergic skin reaction.

4.3. Indication of any immediate medical attention and special treatment needed

All treatments should be based on observed signs and symptoms of distress in the patient.

SECTION 5: Firefighting measures

5.1. Extinguishing media


Unsuitable extinguishing media: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard: No specific fire or explosion hazard.

Explosion hazard: Product is not explosive.

Reactivity: No dangerous reactions known.

5.3. Advice for firefighters

Firefighting instructions: Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection. Wear fire/flame resistant/retardant clothing. Wear a self contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment: Wear suitable gloves. Dust impervious gloves. Chemical goggles or safety glasses.

Emergency procedures: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment: Equip cleanup crew with proper protection. Dust impervious gloves. Chemical goggles or safety glasses.

Emergency procedures: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: On land, sweep or shovel into suitable containers. Minimize generation of dust.

6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust.

Hygiene measures: Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.
7.2. Conditions for safe storage, including any incompatibilities
Storage conditions: Keep only in the original container in a cool well ventilated place. Keep container closed when not in use.
Incompatible products: None known.

7.3. Specific end use(s)
Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
Omeprazole (73590-58-6)
No established Exposure Limits

8.2. Exposure controls
Appropriate engineering controls: Avoid dispersal of dust in the air (ie, clearing dust surfaces with compressed air). Either local exhaust or general room ventilation is usually required.
Personal protective equipment: Avoid all unnecessary exposure.
Hand protection: Wear dust impervious gloves.
Eye protection: In case of dust production: protective goggles.
Skin and body protection: Wear suitable protective clothing. Impervious clothing.
Respiratory protection: Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Use air-purifying respirator equipped with particulate filtering cartridges.
Other information: When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state: Solid
Appearance: Capsules.
Colour: 10mg and 40mg = lavender and yellow; 20mg = lavender and iron grey.
Odour: Odourless.
Odour threshold: No data available
pH: No data available
Relative evaporation rate (butylacetate=1): No data available
Melting point: No data available
Freezing point: No data available
Boiling point: No data available
Flash point: No data available
Self ignition temperature: No data available
Decomposition temperature: No data available
Flammability (solid, gas): No data available
Vapour pressure: No data available
Relative vapour density at 20 °C: No data available
Relative density: No data available
Solubility: No data available
Log Pow: No data available
Log Kow: No data available
Viscosity, kinematic: No data available
Viscosity, dynamic: No data available
Explosive properties: No data available
Oxidising properties: No data available
Explosive limits: No data available

9.2. Other information
No additional information available
SECTION 10: Stability and reactivity

10.1. Reactivity
No dangerous reactions known.

10.2. Chemical stability
The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions
Hazardous polymerization will not occur.

10.4. Conditions to avoid
Extremely high or low temperatures.

10.5. Incompatible materials
None known.

10.6. Hazardous decomposition products
No dangerous decomposition products known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity:
Not classified

Omeprazole Delayed Release Capsules USP 10, 20, 40mg
ATE (oral) 2210.000 mg/kg bodyweight

Omeprazole (73590-58-6)
LD50 oral rat (male) 5010 mg/kg
LD50 oral mice (male) 1520 mg/kg
ATE (oral) 500.000 mg/kg bodyweight

Skin corrosion/irritation:
Not classified

Omeprazole - Mildly irritating to the skin in animal studies.

Serious eye damage/irritation:
Not classified

Respiratory or skin sensitisation:
May cause an allergic skin reaction.

Omeprazole - Strong skin sensitizer in the guinea pig maximization test.

Germ cell mutagenicity:
Not classified

Omeprazole - Omeprazole was positive for clastogenic effects in an in vitro human lymphocyte chromosomal aberration assay, in one of two in vivo mouse micronucleus tests, and in an in vivo bone marrow cell chromosomal aberration assay. Omeprazole was negative in the Ames microbial mutagenicity assay, an in vitro mouse lymphoma cell forward mutation assay, and an in vivo rat liver DNA damage assay.

Carcinogenicity:
Not classified

Omeprazole - Omeprazole was not carcinogenic in chronic studies in mice. In rats tumors of the stomach were seen however these are not considered a significant human risk.

Reproductive toxicity:
Not classified

Omeprazole - Non teratogenic in rats and rabbits; No effects on male and female fertility or reproductive performance in rats at oral doses up to138 mg/kg/day

Specific target organ toxicity (single exposure):
Not classified

Specific target organ toxicity (repeated exposure):
Not classified

Aspiration hazard:
Not classified

Symptoms/injuries after skin contact:
May cause an allergic skin reaction.

Likely routes of exposure:
Ingestion. Inhalation. Dermal.

SECTION 12: Ecological information

12.1. Toxicity
No additional information available.

12.2. Persistence and degradability

Omeprazole Delayed Release Capsules USP 10, 20, 40mg
Persistence and degradability:
Not established.
12.3. Bioaccumulative potential

| Omeprazole Delayed Release Capsules USP 10, 20, 40mg | Bioaccumulative potential | Not established. |

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with DOT
Not a dangerous good in sense of transport regulations

Additional information

Other information : No supplementary information available.

ADR
Transport document description : Not applicable

Transport by sea
No additional information available

Air transport
No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Omeprazole (73590-58-6)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

Omeprazole Delayed Release Capsules USP 10, 20, 40mg
WHMIS Classification | Class D Division 2 Subdivision B - Toxic material causing other toxic effects

Omeprazole (73590-58-6)
Not listed on the Canadian DSL (Domestic Substances List) inventory or the Non-Domestic Substances List.

EU-Regulations

Omeprazole (73590-58-6)
Listed on European List of Notified Chemical Substances (ELINCS)

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Skin Sens. 1 H317
Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC
Not classified

15.2. National regulations

No additional information available

15.3. US State regulations

No additional information available
SECTION 16: Other information

Indication of changes: GHS classification information. Revised sections: 1 - 16.


Abbreviations and acronyms: ACGIH (American Conference of Government Industrial Hygienists).
ATE: Acute Toxicity Estimate.
CAS (Chemical Abstracts Service) number.
CLP: Classification, Labelling, Packaging.
EC50: Environmental Concentration associated with a response by 50% of the test population.
LD50: Lethal Dose for 50% of the test population.
OSHA: Occupational Safety & Health Administration.
TSCA: Toxic Substances Control Act.
STEL: Short Term Exposure Limits.
TWA: Time Weight Average.

Other information: None.

Full text of H-phrases: see section 16:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral) Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Sens. 1</td>
<td>Skin sensitisation Category 1</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
</tr>
</tbody>
</table>

NFPA health hazard: 0 - Exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials.
NFPA fire hazard: 1 - Must be preheated before ignition can occur.
NFPA reactivity: 0 - Normally stable, even under fire exposure conditions, and not reactive with water.

SDS US (GHS HazCom 2012)

SDS prepared by: The Redstone Group, LLC.
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Suite 200
Dublin, Ohio, USA 43016
614.923.7472

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