

### 1. IDENTIFICATION

**Product identifier:** Omeprazole 20mg ODT

**Synonyms:** 1Y9

**Manufacturer Name:** Perrigo Company  
**Address:** 515 Eastern Avenue  
 Allegan, MI 49010 USA

**Telephone number:** 269-673-8451

**Emergency phone number:** 888-464-2986 (U.S. calls)  
 +1 760-476-3962 Code 333304 (International calls)

**Email Address:** SDSRequest@perrigo.com

**Recommended use:** Human drug – Acid Reducer

**Restrictions on use:** Use only as directed.

### 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Skin Sensitization, Category 1A

**Label Elements**

**Warning!**



**Hazard statement(s)**  
 May cause an allergic skin reaction.

**Precautionary statement(s)**

Avoid breathing dust.  
 Contaminated clothing must not be allowed out of the workplace.  
 Wear protective gloves.  
 IF on Skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.  
 Dispose in accordance with local and national regulations

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Omeprazole	73590-58-6	Proprietary
Sodium Stearate	822-16-2	Proprietary
Sodium Stearyl Fumarate	4070-80-8	Proprietary
Titanium Dioxide (bound in tablet matrix)	13463-67-7	Proprietary
Triethyl Citrate	77-93-0	Proprietary

Talc	14807-96-6	Proprietary
Hypromellose	9004-65-3	Proprietary
Flavor	Mixture	Proprietary
Sucralose	56038-13-2	Proprietary
Amino Methacrylate Copolymer	Proprietary	Proprietary
Propylene Glycol	57-55-6	Proprietary
Ascorbic Acid	50-81-7	Proprietary
Cetyl Alcohol	36653-82-4	Proprietary
Colloidal Silicon Dioxide	7631-86-9	Proprietary
Crospovidone	9003-39-8	Proprietary
Ferric Oxide Red	1309-37-1	Proprietary
Hypromellose Phthalate	9050-31-1	Proprietary
Maize Maltodextrin	9050-36-6	Proprietary
Mannitol	69-65-8	Proprietary
Microcrystalline Cellulose	9004-34-6	Proprietary
Silicon Dioxide	60676-86-0	Proprietary
Sorbitol	50-70-4	Proprietary
Sucrose	57-50-1	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. FIRST-AID MEASURES

**Inhalation:** Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.

**Skin contact:** In the case of contact with crushed or broken tablets, remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** In the case of unintended ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur or for overdosage.

**Most important symptoms/effects, acute and delayed:** Dust may cause eye irritation. Inhalation of dust from damaged tablets may cause upper respiratory tract irritation and symptoms similar to ingestion. Swallowing may cause blurred vision; confusion; diaphoresis (increased sweating); drowsiness; dryness of mouth; flushing; headache; malaise (generally feeling of discomfort or illness); nausea; tachycardia (fast /heart beat/ or /arrhythmia/ irregular heartbeat). May cause allergic skin sensitization in exposed workers.

**Indication of immediate medical attention and special treatment, if necessary:** Immediate medical attention is generally not required. For symptoms of sensitization, seek medical advice.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

**Specific hazards arising from the chemical:** Tablets are not a fire hazard but may burn under fire conditions. Fine dust from crushed tablets will present a dust explosion hazard.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8. If tablets are damaged, respiratory protection may be required. Avoid generating airborne dust during cleanup. If dust is present, eliminate all sources of ignition.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Collect using methods that avoid the generation of dust and damage to tablets (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly. If dust is present, do not use vacuum unless explosion-proof.

## 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of dust. If tablets are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging in a secure location.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Omeprazole	50 ug/m3 Perrigo OEL, sensitizer
Sodium Stearate	10 mg/m3 TWA ACGIH TLV
Sodium Stearyl Fumarate	None Established
Titanium Dioxide (bound in capsule matrix)	10 mg/m3 TWA ACGIH TLV 15 mg/m3 (total dust) TWA OSHA PEL
Triethyl Citrate	None Established
Talc	20 mppcf TWA OSHA PEL 2 mg/m3 (respirable dust) TWA ACGIH TLV
Hypromellose	None Established
Flavor	None Established
Sucralose	None Established
Amino Methacrylate Copolymer	None Established
Propylene Glycol	10 mg/m3 TWA AIHA WEEL
Ascorbic Acid	None Established
Cetyl Alcohol	None Established
Colloidal Silicon Dioxide	80 mg/m3 / % SiO2
Crospovidone	None Established
Ferric Oxide Red	5 mg/m3 (respirable dust) ACGIH TLV 10 mg/m3 TWA OSHA PEL (fume)
Hypromellose Phthalate	None Established
Maize Maltodextrin	None Established
Mannitol	None Established
Microcrystalline Cellulose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Silicon Dioxide	None Established
Sorbitol	None Established
Sucrose	10 mg/m3 TWA ACGIH TLV

	5 mg/m <sup>3</sup> (respirable) 15 mg/m <sup>3</sup> (total dust) TWA OSHA PEL
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**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

**Individual protection measures:**

**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** Impervious gloves recommended for handling damaged tablets.

**Eye protection:** Chemical safety goggles recommended for handling damaged tablets.

**Other:** None known.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance (physical state, color, etc.):** Red tablets

**Odor:** None

<b>Odor threshold:</b> Not applicable	<b>pH:</b> Not applicable
<b>Melting point/freezing point:</b> Not applicable	<b>Boiling Point:</b> Not applicable
<b>Flash point:</b> Not applicable	<b>Evaporation rate:</b> Not applicable
<b>Flammability (solid, gas):</b> Not flammable	<b>VOC:</b> Not applicable
<b>Flammable limits: LEL:</b> Not applicable	<b>UEL:</b> Not applicable
<b>Vapor pressure:</b> Not applicable	<b>Vapor density:</b> Not applicable
<b>Relative density:</b> Not available	<b>Solubility(ies):</b> Partially soluble in water
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Viscosity:</b> Not applicable

**10. STABILITY AND REACTIVITY**

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** None known.

**Conditions to avoid:** None known.

**Incompatible materials:** Avoid oxidizing agents.

**Hazardous decomposition products:** Thermal decomposition may yield carbon, sulfur and nitrogen oxides.

**11. TOXICOLOGICAL INFORMATION**

**Acute effects of exposure:**

**Inhalation:** Inhalation of dust from damaged tablets may cause irritation of the mucous membranes and upper respiratory tract and symptoms similar to ingestion.

**Ingestion:** Swallowing may cause blurred vision; confusion; diaphoresis (increased sweating); drowsiness; dryness of mouth; flushing; headache; malaise (generally feeling of discomfort or illness); nausea; tachycardia (fast /heart beat/ or /arrhythmia/ irregular heartbeat).

**Skin contact:** Contact with damaged tablets may cause slight irritation. May cause an allergic skin reaction (sensitization).

**Eye contact:** Contact with damaged tablets may cause slight irritation with redness and tearing.

**Chronic Effects:** None known.

**Sensitization:** Omeprazole is a skin sensitizer.

**Germ Cell Mutagenicity:** None of the components have been shown to cause germ cell mutagenicity. No evidence of mutagenicity was observed in vivo in the rat liver DNA damage assay or in some in vitro test

systems, including the microbial (Ames test) and mammalian (mouse lymphoma) assays. Equivocal results were observed in a micronucleus test and in the chromosome aberration test in mice given omeprazole dosages up to 6250 times the usual human dosage. No evidence of mutagenicity was observed in another micronucleus test in mice given omeprazole dosages up to 2000 times the usual human dosage; however, this finding should be interpreted with caution because suboptimal sampling times were utilized in this study.

**Reproductive Toxicity:** Studies in pregnant rats did not show omeprazole to have any teratogenic potential at doses 345 times the human dose. Omeprazole produced dose-related increases in embryo-lethality, fetal resorptions, and pregnancy disruptions in rabbits receiving 17 to 172 times the human dose. In rats, dose-related embryo/fetal toxicity and postnatal development toxicity were observed in offspring resulting from parents treated with 35 to 345 times the human dose.

**Carcinogenicity:** Titanium dioxide is classified by IARC as a suspected carcinogen (Group 2B). The titanium dioxide is bound in the capsule matrix and no inhalation exposure will occur during the handling of these tablets. None of the other components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. In two 2 year studies in rats, omeprazole, given in doses corresponding to 4 to 352 times the human dose, caused end-life gastric carcinoid tumors and enterochromaffin-like cell hyperplasia in a dose-related manner in both male and female animals. These enterochromaffin-like cell changes have been shown to be caused by high levels of gastrin (or hypergastrinemia). Pronounced acid inhibition at extremely high doses of gastric acid pump inhibitors or H2-receptor antagonists results in the same feedback elevation of gastrin and subsequent enterochromaffin-like cell changes of the stomach.

**Acute Toxicity Values:**

Omeprazole: Oral rat LD50 >4000 mg/kg

<b>12. ECOLOGICAL INFORMATION</b>
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Esomeprazole (an isomer of omeprazole) is classified as chronic aquatic toxicity category 2 under the GHS criteria. It is assumed that omeprazole will have similar aquatic toxicity.

**Ecotoxicity values:** Esomeprazole: ErC50 green algae (*Pseudokirchneriella subcapitata*) 85 mg/L/72 hr (OECD 201); Omeprazole: EC50 daphnia magna >100 mg/L/48 hr (OECD 202), NOEC daphnia magna 10 mg/L/21 d. (OECD 211); LC50 danio rerio 42 mg/L/96 hr; NOEC pimephales promelas 1 mg/L/32 d (OECD 210).

**Persistence and degradability:** Esomeprazole: Not readily biodegradable (<60% in 28 days)

**Bioaccumulative potential:** Esomeprazole: low potential for bioaccumulation (log Kow 2.24)

**Mobility in soil:** Esomeprazole: highly mobile in soil.

**Other adverse effects:** None known.

<b>13. DISPOSAL CONSIDERATIONS</b>
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Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

<b>14. TRANSPORT INFORMATION</b>
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	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
<b>DOT</b>		Not Regulated			
<b>TDG</b>		Not Regulated			
<b>IMDG</b>		Not Regulated			
<b>IATA</b>		Not Regulated			

**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

## 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Refer to section 2 for the OSHA Hazard Classification.

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

## 16. OTHER INFORMATION

**NFPA Rating:** Health = 2      Flammability = 1      Instability = 0  
**HMIS Rating:** Health = 2      Flammability = 1      Physical Hazard = 0

**SDS Revision History:** Correct composition

**Date of preparation:** November 12, 2017

**Disclaimer:** This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).