



## SAFETY DATA SHEET

### 1. IDENTIFICATION

**Product identifier:** Loratadine Oral Solution, Grape, 5 mg/5mL

**Synonyms:** 6T5

**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 –allergy relief

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

### 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Not hazardous

**Label Elements**

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Loratadine	79794-75-5	<1%
Water, purified	7732-18-5	Proprietary
Sorbitol	50-70-4	Proprietary
Propylene Glycol	57-55-6	Proprietary
Glycerin	56-81-5	Proprietary
Sucralose	56038-13-2	Proprietary
Edetate Disodium	6381-92-6	Proprietary
Phosphoric Acid	7664-38-2	Proprietary
Sodium Benzoate	532-32-1	Proprietary
Maltitol	68425-17-2	Proprietary
Monobasic Sodium Phosphate	7558-80-7	Proprietary
Grape Flavor	Mixture	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:** First aid is not generally required for skin contact. 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 overdose.

**Most important symptoms/effects, acute and delayed:** May cause mild eye irritation. Swallowing amounts above the recommended dosage may cause gastrointestinal effects, drowsiness, nervousness, dizziness and sleeplessness.

**Indication of immediate medical attention and special treatment, if necessary:** Medical attention is recommended for large unintended ingestion.

#### 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:** This product is not a fire hazard but may burn under fire conditions after the water has evaporated.

**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. Cool fire exposed containers with water.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8. Caution – spilled liquid may present a slip hazard.

**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 liquid with an inert absorbent and place in appropriate container for disposal. Clean area thoroughly.

#### 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling. If large amounts are handled, use adequate ventilation.

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

<b>8. EXPOSURE CONTROLS / PERSONAL PROTECTION</b>
---

**Exposure guidelines:**

Loratadine	10-100 ug/m <sup>3</sup> TWA (Perrigo OEB3)
Water, purified	None Established
Sorbitol	None Established
Propylene Glycol	10 mg/m <sup>3</sup> TWA AIHA WEEL
Glycerin	5 mg/m <sup>3</sup> (respirable particulate) TWA OSHA PEL 15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL
Sucralose	None Established
Edetate Disodium	None Established
Phosphoric Acid	1 mg/m <sup>3</sup> TWA OSHA PEL 1 mg/m <sup>3</sup> TWA 3 mg/m <sup>3</sup> STEL ACGIH TLV
Sodium Benzoate	None Established
Maltitol	None Established
Monobasic Sodium Phosphate	None Established
Grape Flavor	None Established

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits.

**Individual protection measures:**

**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved organic vapor or supplied air 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:** None required for normal use. Impervious gloves recommended for bulk handling.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for bulk handling.

**Other:** None known.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>
--

**Appearance (physical state, color, etc.):** Colorless to light yellow liquid

**Odor:** Grape odor

<b>Odor threshold:</b> Not available	<b>pH:</b> 2.4-2.8
<b>Melting point/freezing point:</b> Not available	<b>Boiling Point:</b> Not available
<b>Flash point:</b> None	<b>Evaporation rate:</b> Same as water
<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> Not available
<b>Flammable limits: LEL:</b> Not applicable	<b>UEL:</b> Not applicable
<b>Vapor pressure:</b> Same as water	<b>Vapor density:</b> Same as water
<b>Relative density:</b> 1.19-1.29	<b>Solubility(ies):</b> Completely 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 available

<b>10. STABILITY AND REACTIVITY</b>
-------------------------------------

**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 oxides.

## 11. TOXICOLOGICAL INFORMATION

### **Acute effects of exposure:**

**Inhalation:** Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract.

**Ingestion:** Swallowing amounts above the recommended dosage may cause gastrointestinal effects, drowsiness, nervousness, dizziness and sleeplessness.

**Skin contact:** Contact may cause slight irritation.

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

**Chronic Effects:** None known.

**Sensitization:** Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

**Germ Cell Mutagenicity:** None of the components have been shown to cause germ cell mutagenicity. In mutagenicity studies with Loratadine, there was no evidence of mutagenic potential in reverse (Ames) or forward point mutation (CHO-HGPRT) assays, or in the assay for DNA damage (rat Primary Hepatocyte Unscheduled DNA Assay) or in two assays for chromosomal aberrations (Human Peripheral Blood Lymphocyte Clastogenesis Assay and the Mouse Bone Marrow Erythrocyte Micronucleus Assay). In the Mouse Lymphoma Assay, a positive finding occurred in the nonactivated but not the activated phase of the study.

**Reproductive Toxicity:** None of the components are reproductive toxins. There was no evidence of animal teratogenicity in studies with loratadine performed in rats and rabbits at oral doses up to 96 mg/kg. Decreased fertility in male rats, shown by lower female conception rates, occurred at approximately 64 mg/kg and was reversible with cessation of dosing. Loratadine had no effect on male or female fertility or reproduction in the rat at doses of approximately 24 mg/kg.

**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. In an 18 month oncogenicity study in mice and a 2 year study in rats, loratadine was administered in the diet at doses up to 40 mg/kg (mice) and 25 mg/kg (rats). Male mice given 40 mg/kg had a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) than concurrent controls. In rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg and males and females given 25 mg/kg. The clinical significance of these findings during long-term use of loratadine tablets is not known.

**Acute Toxicity Values:** Loratadine: Oral rat LD50 >5000 mg/kg

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity values:** No data is available

**Persistence and degradability:** No data is available

**Bioaccumulative potential:** No data is available

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

<b>14. TRANSPORT INFORMATION</b>
----------------------------------

	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.

<b>15. REGULATORY INFORMATION</b>
-----------------------------------

**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):** Not Hazardous

**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.

<b>16. OTHER INFORMATION</b>
------------------------------

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

**SDS Revision History:** New SDS

**Date of preparation:** January 23, 2018

**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).