



Quality Affordable Healthcare Products™

## SAFETY DATA SHEET

### 1. IDENTIFICATION

**Product identifier:** ORA-SWEET®

**Synonyms:** 3X8

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

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

**Emergency phone number:** 888-464-2986

**Recommended use:** Used in the preparation of oral, suspended, aqueous dosage forms

**Restrictions on use:** None known.

**Date of Preparation:** August 22, 2014

### 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
Water, purified	7732-18-5	Proprietary
Sucrose	57-50-1	Proprietary
Sorbitol	50-70-4	Proprietary
Glycerin	56-81-5	Proprietary
Berry Citrus Flavor	Mixture	Proprietary
Monobasic sodium phosphate	7558-80-7	Proprietary
Citric Acid	77-92-9	Proprietary
Potassium sorbate	24634-61-5	Proprietary
Methylparaben	99-76-3	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, 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:** No adverse effects are expected. No first aid required.

**Most important symptoms/effects, acute and delayed:** May cause mild eye irritation.

**Indication of immediate medical attention and special treatment, if necessary:** Immediate medical attention is required 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:** None required.

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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Water, purified	None Established
Sucrose	10 mg/m <sup>3</sup> TWA ACGIH TLV 5 mg/m <sup>3</sup> (respirable particulate) TWA OSHA PEL 15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL
Sorbitol	None Established
Glycerin	5 mg/m <sup>3</sup> (respirable particulate) TWA OSHA PEL 15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL
Berry Citrus Flavor	None Established
Monobasic sodium phosphate	None Established
Citric Acid	None Established

Potassium sorbate	None Established
Methylparaben	500 ug/m3 Perrigo OEL

**Appropriate engineering controls:** No special requirements. Use with adequate general or local exhaust ventilation to keep exposures below minimize exposure levels.

**Individual protection measures:**

**Respiratory protection:** None needed under normal use conditions.

**Skin protection:** None required for normal use.

**Eye protection:** None required for normal use.

**Other:** None known.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance (physical state, color, etc.):** Light pink liquid

**Odor:** Citrus/berry

<b>Odor threshold:</b> Not available	<b>pH:</b> 4.2
<b>Melting point/freezing point:</b> Not available	<b>Boiling Point:</b> Not available
<b>Flash point:</b> None	<b>Evaporation rate:</b> Not available
<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> Not available	<b>Vapor density:</b> Not available
<b>Relative density:</b> Not available	<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

**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 oxides.

**11. TOXICOLOGICAL INFORMATION**

**Acute effects of exposure:**

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

**Ingestion:** No adverse effects are expected.

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

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

**Chronic Effects:** No adverse effects are expected.

**Sensitization:** Components are not known to be sensitizers.

**Germ Cell Mutagenicity:** None of the components have been shown to cause germ cell mutagenicity.

**Reproductive Toxicity:** None of the components have been shown to cause reproductive effects.

**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA.

**Acute Toxicity Values:** Not acutely toxic based on a review of the components.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity values:** No toxicity to aquatic organisms is expected.

**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.

**14. TRANSPORT INFORMATION**

	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):** 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 an FDA product and not subject to TSCA.

**CANADA:**

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

**Canadian WHMIS Classification:** Not a controlled product

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

**16. OTHER INFORMATION**

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

**SDS Revision History:** Convert to OSHA Hazcom 2012 format and content

**Date of preparation:** August 22, 2014

**Date of last revision:** January 28, 2013

**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).