

SAFETY DATA SHEETS

This SDS packet was issued with item:

078435137

N/A



Quality Affordable Healthcare Products™

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: ORA-SWEET®

Synonyms: 3X8

Global Contact: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: +1 269-673-8451
Emergency telephone: +1 888-464-2986

Australian Contact: Perrigo Australia
Address: 25-29 Delawney Street
Balcatta, Western Australia 6021 Australia

Telephone number: +618 9441 7800
Emergency telephone: +1 760-476-3962 Code 333304 or Poisons Information Centre: 13 11 26

New Zealand Contact: Orion Laboratories (NZ) Pty Ltd
Address: PO Box 781
Whangaparaoa, New Zealand

Telephone number: +618 9441 7800
Emergency telephone: +1 760-476-3962 Code 333304 or National Poisons Centre: 0800 764 766

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

Restrictions on use: None known.

HSNO Number: Not applicable

Date of Preparation: April 17, 2015

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Label Elements

Not hazardous in accordance with the GHS.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration	Substance Classification
Water, purified	7732-18-5	Proprietary	Not Hazardous
Sucrose	57-50-1	Proprietary	Not Hazardous
Sorbitol	50-70-4	Proprietary	Not Hazardous
Glycerin	56-81-5	Proprietary	Not Hazardous
Berry Citrus Flavor	Mixture	Proprietary	Not Hazardous
Monobasic sodium phosphate	7558-80-7	Proprietary	Not Hazardous
Citric Acid	77-92-9	Proprietary	Eye Irrit. Category 2 (H319, 6.4A)
Potassium sorbate	24634-61-5	Proprietary	Skin Irrit. Category 2 (H315, 6.3A) Eye Irrit. Category 2 (H319, 6.4A)
Methylparaben	99-76-3	Proprietary	Aq. Chronic Category 3 (H412, 9.1C)

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/m3 TWA ACGIH TLV 10 mg/m3 TWA AU OEL 10 mg/m3 TWA NZ OEL
Sorbitol	None Established
Glycerin	10 mg/m3 TWA AU OEL 10 mg/m3 TWA NZ OEL
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

Odor threshold: Not available	pH: 4.2
Melting point/freezing point: Not available	Boiling Point: Not available
Flash point: None	Evaporation rate: Not available
Flammability (solid, gas): Not applicable	VOC: Not available
Flammable limits: LEL: Not applicable	UEL: Not applicable
Vapor pressure: Not available	Vapor density: Not available
Relative density: Not available	Solubility(ies): Completely soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: 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, or ACGIH.

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
IMDG		Not Regulated			
IATA		Not Regulated			
ADG		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.

New Zealand Inventory: All ingredients comply with or exempt from HSNO regulations.

Australia Inventory:

16. OTHER INFORMATION

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

SDS Revision History: New AU/NZ SDS

Date of preparation: April 17, 2015

Date of last revision: N/A

Full Text of GHS Classification and H Phrases from Section 3:

Aq. Chronic Cat 3 Aquatic Chronic Toxicity Category 3

Eye Irrit. Cat 2 Eye Irritant Category 2

Skin Irrit. Cat 2 Skin Irritant Category 2

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H411 Harmful to aquatic life with long lasting effects.

List of Abbreviations or Acronyms:

ACGIH American Conference of Industrial Hygienists

ADG Australian Dangerous Goods

AICS Australian Inventory of Chemical Substances

AU Australia

EC Effective Concentration

EU European Union

GHS Globally Harmonized System of Classification and Labelling of Chemicals

HSNO Hazardous Substances and New Organisms

IARC International Agency of Research on Cancer

IATA International Air Transport Association

IMDG International Maritime Dangerous Goods

LC Lethal Concentration

LD Lethal Dosage
LEL Lower Explosive Limit
NTP National Toxicology Program
NZ New Zealand
OEL Occupational Exposure Limits
US OSHA United States Occupational Safety and Health Administration
PEL Permissible Exposure Limit
SDS Safety Data Sheet
STEL Short Term Exposure Limit
TWA Time-Weighted Average
UEL Upper Explosive Limit
VOC Volatile Organic Compounds
WES Workplace Exposure Standards
WHS Work Health and Safety

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