

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Cough DM – Dextromethorphan Suspension, Orange and Grape
Synonyms: 384, 958, 494, 899

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 – Cough Suppressant
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Acute Oral Toxicity Category 4

Label Elements

Warning



Hazard statement(s)

Harmful if swallowed.

Precautionary statement(s)

Do not eat, drink or smoke when using this product.
 IF Swallowed: Call a poison center or doctor if you feel unwell. Rinse mouth.
 Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Dextromethorphan Polistirex	125-71-3	30%
Water	7732-18-5	Proprietary
High Fructose Corn Syrup	8029-43-4	Proprietary
Glycerin	56-81-5	Proprietary
Sucrose	57-50-1	Proprietary
Flavor	Mixture	Proprietary
FD&C Red #30 Aluminum Lake	1342-90-1	Proprietary

Cough DM – Dextromethorphan Suspension, Orange and Grape
384, 958, 494, 899

D&C Yellow #10 Aluminum Lake (orange only)	38615-46-2	Proprietary
FD&C Blue #1 Aluminum Lake (grape only)	68921-42-6	Proprietary
Methylparaben	99-76-3	Proprietary
Propylparaben	94-13-3	Proprietary
Polysorbate 80	89964-07-8	Proprietary
Polyvinyl Acetate	9003-20-7	Proprietary
Povidone	9003-39-8	Proprietary
Sodium Metabisulfite	7681-57-4	Proprietary
Sodium Polystyrene Sulfonate	25704-18-1	Proprietary
Tartaric Acid	133-37-9	Proprietary
Tragacanth Gum	9000-65-1	Proprietary
Triacetin	102-76-1	Proprietary
Xanthan Gum	11138-66-2	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 caplets, 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 overdose.

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

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: Avoid contact with eyes, skin and clothing. 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:

Dextromethorphan Polistirex	Perrigo OEB2 100-1000 ug/m3 TWA
Water	None Established
High Fructose Corn Syrup 1	None Established
Glycerin	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Sucrose	
Flavor	None Established
FD&C Red #30 Aluminum Lake	None Established
D&C Yellow #10 Aluminum Lake (orange only)	None Established
FD&C Blue #1 Aluminum Lake (grape only)	None Established
Methylparaben	500 ug/m3 Perrigo OEB2
Propylparaben	None Established
Polysorbate 80	None Established
Polyvinyl Acetate	None Established
Povidone	None Established
Sodium Metabisulfite	5 mg/m3 TWA ACGIH TLV
Sodium Polystyrene Sulfonate	None Established
Tartaric Acid	None Established
Tragacanth Gum	None Established
Triacetin	None Established
Xanthan Gum	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 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.

Cough DM – Dextromethorphan Suspension, Orange and Grape
384, 958, 494, 899

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Orange or purple liquid

Odor: Orange or grape

Odor threshold: Not available	pH: 3.9
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 irritation of the mucous membranes and upper respiratory tract.

Ingestion: May be harmful if swallowed. Swallowing amounts above the recommended dosage may cause gastrointestinal effects, nervousness, dizziness and sleeplessness.

Skin contact: Contact may cause irritation.

Eye contact: Contact may cause 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.

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: Acute Oral Toxicity Estimate (ATE) calculated: 1167 mg/kg

Dextromethorphan Polistirex: Oral rat LD50 350 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.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		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): Acute Health

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

SDS Revision History: updated CAS #s

Date of preparation: April 29, 2019

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).