

### 1. IDENTIFICATION

**Product identifier:** Guaifenesin 600mg Dex 30mg Tablets (219/93C)  
 Guaifenesin 1200mg Dex 60mg Tablets (812/0S8/61U/73D)

**Synonyms:** 0S8, 219, 61U, 812, 93C, 73D

**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 – Expectorant and Cough Suppressant

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

### 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Acute Toxicity Category 4 (oral)

**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
Guaifenesin	93-14-1	70-80%
Dextromethorphan HBr	6700-34-1	<4%
Microcrystalline Cellulose	9004-34-6	Proprietary
Colloidal Silicon Dioxide	7631-86-9	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Copovidone	25086-89-9	Proprietary
Carbomer Homopolymer Type B	584-08-7	Proprietary
Hypromellose	9004-65-3	Proprietary
Magnesium Hydroxide	1309-42-8	Proprietary
D&C Yellow #10 Aluminum Lake	68814-04-0	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:** 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 broken tablets may cause upper respiratory tract irritation and symptoms similar to ingestion. Swallowing amounts above the recommended dosage may cause gastrointestinal disturbance and nervous system effects with nausea, dizziness, nervousness, restlessness and drowsiness.

**Indication of immediate medical attention and special treatment, if necessary:** 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:** 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.

**Guaifenesin 600mg Dex 30mg Tablets (219/93C)**  
**Guaifenesin 1200mg Dex 60mg Tablets (812/0S8/61U/73D)**

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Exposure guidelines:**

Guaifenesin	1000 µg/m <sup>3</sup> TWA Perrigo OEL (OEB1)
Dextromethorphan HBr	50 ug/m <sup>3</sup> TWA (Perrigo OEL)
Microcrystalline Cellulose	10 mg/m <sup>3</sup> TWA ACGIH TLV 15 mg/m <sup>3</sup> TWA OSHA PEL total dust 5 mg/m <sup>3</sup> TWA OSHA PEL respirable fraction
Colloidal Silicon Dioxide	80 mg/m <sup>3</sup> /%SiO <sub>2</sub> TWA OSHA PEL
Magnesium Stearate	10 mg/m <sup>3</sup> TWA ACGIH TLV
Copovidone	None Established
Carbomer Homopolymer Type B	None Established
Hypromellose	None Established
Magnesium Hydroxide	None Established
D&C Yellow #10 Aluminum Lake	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 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.):** Yellow 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> Partly 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 oxide and bromine compounds.

**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 effects similar to ingestion.

**Ingestion:** Swallowing amounts above the recommended dosage may cause gastrointestinal disturbance and nervous system effects with nausea, dizziness, nervousness, restlessness and drowsiness. Harmful if swallowed.

**Skin contact:** Contact with damaged tablets may cause slight irritation.

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

**Chronic Effects:** None known.

**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:** Components are not reproductive toxins.

**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: 1563 mg/kg

Guaifenesin: Oral rat LD50 1510 mg/kg

Dextromethorphan Hydrobromide: Oral rat LD50 350 mg/kg

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity values:** No data 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**

	<b>UN Number</b>	<b>Proper shipping name</b>	<b>Hazard Class</b>	<b>Packing Group</b>	<b>Environmental Hazard</b>
<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 reporting requirements. 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 = 1      Flammability = 1      Instability = 0  
**HMIS Rating:** Health = 1      Flammability = 1      Physical Hazard = 0

**SDS Revision History:** updated Synonym-61U

**Date of preparation:** April 15, 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).