



## SAFETY DATA SHEET

### 1. IDENTIFICATION

**Product identifier:** Children's Pain Reliever Oral Suspension, Grape Flavor

**Synonyms:** 130

**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 – Pain and fever reliever

**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 |
|-------------------------------|-----------|---------------|
| Acetaminophen                 | 103-90-2  | 2.5%          |
| Water, purified               | 7732-18-5 | Proprietary   |
| Glycerin                      | 56-81-5   | Proprietary   |
| Propylene Glycol              | 57-55-6   | Proprietary   |
| High Fructose Corn Syrup      | 57-48-7   | Proprietary   |
| Microcrystalline Cellulose    | 9004-34-6 | Proprietary   |
| Sorbitol                      | 50-70-4   | Proprietary   |
| Citric Acid                   | 77-92-9   | Proprietary   |
| Sodium Benzoate               | 532-32-1  | Proprietary   |
| Carboxymethylcellulose Sodium | 9004-32-4 | Proprietary   |
| Tribasic Sodium Phosphate     | 7601-54-9 | Proprietary   |
| Hydroxyethyl Cellulose        | 9004-62-0 | Proprietary   |
| Butylparaben                  | 94-26-8   | Proprietary   |

|                 |            |             |
|-----------------|------------|-------------|
| Calcium Sulfate | 10101-41-4 | Proprietary |
| Carrageenan     | 9000-07-1  | Proprietary |
| D&C Red #33     | 3567-66-6  | Proprietary |
| FD&C Blue #1    | 3844-45-9  | Proprietary |
| Flavors         | 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. Large ingestions or prolonged use may damage the liver.

**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:**

|                               |  |
|-------------------------------|--|
| Acetaminophen                 | 4000 ug/m <sup>3</sup> TWA (Perrigo OEB1)  |
| Water, purified               | None Established   |
| Glycerin                      | 5 mg/m <sup>3</sup> (respirable particulate) TWA OSHA PEL<br>15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL   |
| Propylene Glycol              | 10 mg/m <sup>3</sup> TWA AIHA WEEL   |
| High Fructose Corn Syrup      | 1000 ppm TWA OSHA PEL<br>1000 ppm STEL ACGIH TLV   |
| Microcrystalline Cellulose    | 5 mg/m <sup>3</sup> (respirable particulate) TWA OSHA PEL<br>15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL<br>10 mg/m <sup>3</sup> TWA ACGIH TLV             |
| Sorbitol                      | None Established   |
| Citric Acid                   | None Established   |
| Sodium Benzoate               | None Established   |
| Carboxymethylcellulose Sodium | None Established   |
| Tribasic Sodium Phosphate     | None Established   |
| Hydroxyethyl Cellulose        | None Established   |
| Butylparaben                  | None Established   |
| Calcium Sulfate               | 5 mg/m <sup>3</sup> (respirable particulate) TWA OSHA PEL<br>15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL<br>10 mg/m <sup>3</sup> (inhalable) TWA ACGIH TLV |
| Carrageenan                   | None Established   |
| D&C Red #33                   | None Established   |
| FD&C Blue #1                  | None Established   |
| Flavors                       | 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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance (physical state, color, etc.):** Light purple with a pink hue liquid

**Odor:** Sweet, grape odor

|  |   |
|--|---|
| <b>Odor threshold:</b> Not available                         | <b>pH:</b> 4.5                                      |
| <b>Melting point/freezing point:</b> Not available           | <b>Boiling Point:</b> Not available                 |
| <b>Flash point:</b> 482°F (closed cup)                       | <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> 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 irritation of the mucous membranes and upper respiratory tract.

**Ingestion:** Swallowing amounts above the recommended dosage may cause gastrointestinal effects.

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

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

**Chronic Effects:** Large ingestions or prolonged use may damage the liver.

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

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

Acetaminophen was not mutagenic in in-vitro bacterial reverse mutation assays and the drosophila SLRL test but indices sister chromatid exchange and chromosomal aberration in in-vitro and in-vivo tests with human cells. It was negative in an in-vivo mouse micronucleus assay.

**Reproductive Toxicity:** Acetaminophen did not cause effects on reproductive performance or development in studies with rats but cause some developmental toxicity in mice. The significance of this finding to humans is not known.

**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. Acetaminophen was tested for carcinogenicity in rats and mice with no evidence of carcinogenic effect.

**Acute Toxicity Values:** Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Acetaminophen: Oral rat LD50 1944 mg/kg

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity values:** Acetaminophen: EC50 daphnia magna 6.1-14 mg/L/48 hr.; LC50 fathead minnow 814 mg/L/96 hr.

**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.

|                                    |
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| <b>13. DISPOSAL CONSIDERATIONS</b> |
|------------------------------------|

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:** Convert to OSHA Hazcom 2012 format and content

**Date of preparation:** November 15, 2015

**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).