



SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: DAYTIME COLD & FLU NON-DROWSY LIQUID

Synonyms: 656

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: Human drug – Nasal Decongestant, Cough Suppressant, Pain Reliever, Fever Reducer

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 | 1.8% |
| Dextromethorphan Hydrobromide | 125-69-9 | <0.1% |
| Phenylephrine Hydrochloride | 61-76-7 | <0.1% |
| Sucrose | 57-50-1 | Proprietary |
| Water, purified | 7732-18-5 | Proprietary |
| Propylene Glycol | 57-55-6 | Proprietary |
| Glycerin | 56-81-5 | Proprietary |
| Polyethylene Glycol | 25322-68-3 | Proprietary |
| Artificial Fruit Flavor | Mixture | Proprietary |
| Monobasic sodium phosphate | 7558-80-7 | Proprietary |
| Sodium saccharin | 6155-57-3 | Proprietary |
| FD&C Yellow #6 | 2783-94-0 | Proprietary |
| Disodium EDTA | 6381-92-6 | Proprietary |
| Butylated Hydroxyanisole | 121-00-6 | <0.1% |
| Menthol | 2216-51-5 | 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: 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 overdosage.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Swallowing amounts above the recommended dosage may cause gastrointestinal effects, nervousness, dizziness and sleeplessness. Large ingestions or prolonged use may damage the liver and kidneys.

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 ³ TWA (Perrigo OEB1) |
| Dextromethorphan Hydrobromide | 100 ug/m ³ TWA (Perrigo OEB2) |
| Phenylephrine Hydrochloride | 30 ug/m ³ TWA (Perrigo OEB3) |
| Sucrose | 10 mg/m ³ TWA ACGIH TLV 15 mg/m ³ (total dust) TWA OSHA PEL 5 mg/m ³ (respirable dust) TWA OSHA PEL |
| Water, purified | None Established |
| Propylene Glycol | 10 mg/m ³ TWA AIHA WEEL |
| Glycerin | 5 mg/m ³ (respirable particulate) TWA OSHA PEL 15 mg/m ³ (total particulate) TWA OSHA PEL |
| Polyethylene Glycol | 10 mg/m ³ TWA AIHA WEEL |
| Artificial Fruit Flavor | None Established |
| Monobasic sodium phosphate | None Established |
| Sodium saccharin | None Established |
| FD&C Yellow #6 | None Established |
| Disodium EDTA | None Established |
| Butylated Hydroxyanisole | None Established |
| Menthol | None Established |
| Xanthan Gum (as PNOC) | 5 mg/m ³ (respirable particulate) TWA OSHA PEL 15 mg/m ³ (total particulate) TWA OSHA PEL |

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: 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 Liquid

Odor: Menthol/fruity

| | |
|--|---|
| Odor threshold: Not available | pH: 4.97 |
| 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: Swallowing amounts above the recommended dosage may cause gastrointestinal effects, nervousness, dizziness and sleeplessness.

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 and kidney.

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.

Acetaminophen was not mutagenic in in-vitro bacterial reverse mutation assays and the drosophila SLRL test but induced 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: 52,632 mg/kg

Acetaminophen: Oral rat LD50 1944 mg/kg

Dextromethorphan Hydrobromide: Oral rat LD50 350 mg/kg

Phenylephrine Hydrochloride: Oral rat LD50 350 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.

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): 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.

16. OTHER INFORMATION

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

SDS Revision History: New SDS

Date of preparation: July 25, 2016

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).

1. IDENTIFICATION

Product identifier: NIGHTTIME FREE CHERRY FLAVOR 6HR LIQUID

Synonyms: 459

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 – Antihistamine, Cough Suppressant, Pain Reliever, Fever Reducer

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

| Physical | Health |
|-----------------------------|---------------|
| Flammable Liquid Category 3 | Not hazardous |

Label Elements

Warning!



Hazard statement(s)

Flammable liquid and vapor.

Precautionary statement(s)

Keep away from heat, sparks, open flames and hot surfaces. No smoking.
 Keep container tightly closed.
 Ground and bond container and receiving equipment.
 Use explosion-proof electrical, ventilating and lighting equipment.

Precautionary statement(s)

Use only non-sparking tools.
 Take precautionary measures against static discharge.
 Wear protective gloves and eye protection.
 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
 In case of fire: Use water spray, carbon dioxide or alcohol-resistant foam to extinguish.
 Store in a well-ventilated place. Keep cool.
 Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical name | CAS No. | Concentration |
|-------------------------------|------------|---------------|
| Acetaminophen | 103-90-2 | 1.8% |
| Dextromethorphan Hydrobromide | 125-69-9 | 0.1% |
| Doxylamine Succinate | 562-10-7 | <0.1% |
| High Fructose Corn Syrup | 57-48-7 | Proprietary |
| Water, purified | 7732-18-5 | Proprietary |
| Polyethylene Glycol | 25322-68-3 | Proprietary |
| Propylene Glycol | 57-55-6 | Proprietary |
| Ethanol | 64-17-5 | 5-10% |
| Citric Acid | 77-92-9 | Proprietary |
| Sodium Citrate | 68-04-2 | Proprietary |
| Artificial Cherry Flavor | Mixture | Proprietary |
| FD&C Blue #1 | 3844-45-9 | Proprietary |
| FD&C Red #40 | 25956-17-6 | Proprietary |
| Sodium saccharin | 6155-57-3 | 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 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, nervousness, dizziness and drowsiness. Large ingestions or prolonged use may damage the liver and kidneys. Inhalation of ethanol vapors may cause dizziness and drowsiness.

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 fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam.

Specific hazards arising from the chemical: Flammable liquid and vapor. Vapors are heavier than air and can flow to remote ignition sources and flash back. Vapors may be explosive in confined areas. Vapors will collect in low areas. Vapors may be ignited by static sparks. Flames may be invisible in daylight.

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. Eliminate all ignition sources and ventilate the area with explosion-proof equipment. Prevent entry into basements or confined areas.

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: Stop spill at the source if it is safe to do so. Absorb with an inert material. Use non-sparking tools and equipment. Collect into a suitable container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid eye and skin contact. Avoid breathing vapors. Use only with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use. Keep product away from heat, sparks and all other sources of ignition. Electrically bond and ground transfer equipment, Use appropriately rated electrical equipment in areas where this material is handled and stored. Keep containers closed when not in use.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging. Protect containers from physical damage. Store in a cool area. Keep away from excessive heat and open flames. Keep containers closed when not in use. Store away from oxidizers.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

| | |
|-------------------------------|--|
| Acetaminophen | 4000 ug/m ³ TWA (Perrigo OEL) |
| Dextromethorphan Hydrobromide | 50 ug/m ³ TWA (Perrigo OEL) |
| Doxylamine Succinate | 25 ug/m ³ TWA (Perrigo OEL) |
| High Fructose Corn Syrup | None Established |
| Polyethylene Glycol | None Established |
| Propylene Glycol | 10 mg/m ³ TWA AIHA WEEL |
| Ethanol | 1000 ppm TWA OSHA PEL 1000 ppm STEL ACGIH TLV |
| Citric Acid | None Established |
| Sodium Citrate | None Established |
| Artificial Cherry Flavor | None Established |
| FD&C Blue #1 | None Established |
| FD&C Red #40 | None Established |
| Sodium saccharine | 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: 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.): Dark Red Liquid

Odor: Cherry

| | |
|--|---|
| Odor threshold: 100 ppm (Ethanol) | pH: 5.3 |
| Melting point/freezing point: Not available | Boiling Point: Not available |
| Flash point: 57.8°C (136°F) (Closed Cup) | Evaporation rate: Not available |
| Flammability (solid, gas): Not applicable | VOC: Not available |
| Flammable limits: LEL: 3% (ethanol) | UEL: 19% (ethanol) |
| Vapor pressure: 59.3 mmHg @ 25°C (ethanol) | Vapor density: 1.59 (ethanol) |
| 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 vapors may cause minor irritation of the mucous membranes and upper respiratory tract and central nervous system effects such as dizziness, drowsiness and headache.

Ingestion: Swallowing amounts above the recommended dosage may cause gastrointestinal effects, nervousness, dizziness and drowsiness.

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 and kidney.

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. Acetaminophen was not mutagenic in in-vitro bacterial reverse mutation assays and the drosophila SLRL test but induced 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: Components are not reproductive toxins. 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: >5,000 mg/kg
Acetaminophen: Oral rat LD50 1944 mg/kg

Dextromethorphan Hydrobromide: Oral rat LD50 350 mg/kg
Doxylamine Succinate: Oral rat LD50 600 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.

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 | None | Not regulated per aqueous alcohol exception | None | | No |
| TDG | None | Not regulated per aqueous alcohol exception | None | | No |
| IMDG | None | Not regulated per aqueous alcohol exception | None | | No |
| IATA | None | Not regulated per aqueous alcohol exception | None | | No |

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): Fire Hazard

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 = 2 Instability = 0

HMIS Rating: Health = 1 Flammability = 2 Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: March 24, 2016

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).