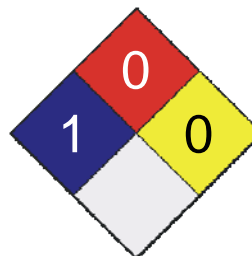


1. Product and Company Identification

Product Name CEPAOL® Sore Throat & Cough Lozenges - Mixed Berry
CAS # Mixture
Product use Sore Throat - Oral anesthetic/analgesic/antiseptic lozenge
Distributed by Reckitt Benckiser
 Morris Corporate Center IV
 399 Interpace Parkway
 P.O. Box 225
 Parsippany, NJ 07054-0225
 In Case of Emergency: 1-800-338-6167
 Transportation Emergencies: 24 Hour Number:
 North America: CHEMTREC: 1-800-424-9300
 Outside North America: 1-703-527-3887

LEGEND HMIS/NFPA	
Severe	4
Serious	3
Moderate	2
Slight	1
Minimal	0

Health	/ 1
Flammability	0
Physical Hazard	0
Personal Protection	



2. Hazards Identification

Emergency overview

This product is regulated by the US FDA as an over-the-counter, monograph drug.

WARNINGS: Allergy Alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or any other 'caine' anesthetics.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly.

Do not use in a child under 6 years of age.

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking the product.

Ask a doctor before use if you have:
 persistent or chronic cough such as occurs with smoking, asthma, or emphysema.
 cough that is accompanied by excessive phlegm (mucus)

Stop use and ask a doctor or dentist if:
 sore mouth symptoms do not improve in 7 days
 irritation, pain or redness persists or worsens
 swelling develops
 cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast feeding, ask a health professional before use.
 Keep this and all drugs out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
 Do not exceed recommended dosage.
KEEP OUT OF REACH OF CHILDREN.

Potential short term health effects

Routes of exposure

Eye, Skin contact, Inhalation, Ingestion.

Eyes

There is no known adverse effect from exposure to the recommended use of this product.

Skin

There is no known adverse effect from exposure to the recommended use of this product.

Inhalation	There is no known adverse effect from exposure to the recommended use of this product.
Ingestion	There is no known adverse effect from exposure to the recommended use of this product.
Target organs	Not applicable.
Chronic effects	The finished product is not expected to have chronic health effects.
Signs and symptoms	There are no hazards associated with this product in normal use.
OSHA Regulatory Status	This product is NOT known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
Potential environmental effects	This product has not been tested.

3. Composition / Information on Ingredients

Ingredient(s)	CAS #	Percent
Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	40 - 60
Benzocaine	94-09-7	0.1 - 1
Dextromethorphan hydrobromide	6700-34-1	0.1 - 1

4. First Aid Measures

First aid procedures	
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
Skin contact	Wash with soap and water. Get medical attention if irritation develops or persists.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get immediate medical attention.
Ingestion	Not applicable. Get medical attention immediately if adverse effects are felt.
Notes to physician	Symptoms may be delayed.
General advice	If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Keep out of reach of children.

5. Fire Fighting Measures

Flammable properties	Not flammable by OSHA criteria.
Extinguishing media	
Suitable extinguishing media	Water spray. Dry chemical. Carbon dioxide. Alcohol foam.
Unsuitable extinguishing media	Not available
Protection of firefighters	
Specific hazards arising from the chemical	Not available
Protective equipment for firefighters	Firefighters should wear full protective clothing including self contained breathing apparatus.
Hazardous combustion products	May include and are not limited to: Oxides of carbon. Oxides of nitrogen. Oxides of sulphur. Oxides of sodium.
Explosion data	
Sensitivity to mechanical impact	Not available
Sensitivity to static discharge	Not available

6. Accidental Release Measures

Personal precautions	Keep unnecessary personnel away. Do not touch or walk through spilled material.
Environmental precautions	Do not discharge into lakes, streams, ponds or public waters.
Methods for containment	Prevent entry into waterways, sewers, basements or confined areas.
Methods for cleaning up	Pick up and discard.

7. Handling and Storage

Handling	Use good industrial hygiene practices in handling this material. Use according to package label instructions. Tamper evident: Product is sealed in blister package for your protection. Do not use if carton is damaged or if printed seal on blister is broken or missing.
Storage	Protect contents from humidity. Store at room temperature (68-77°F)(20-25°C). Keep out of reach of children.

8. Exposure Controls / Personal Protection

Exposure limits

Ingredient(s)	Exposure Limits
Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	ACGIH-TLV TWA: 10 mg/m ³ OSHA-PEL TWA: 15 mg/m ³
Benzocaine	ACGIH-TLV Not established OSHA-PEL Not established
Dextromethorphan hydrobromide	ACGIH-TLV Not established OSHA-PEL Not established
Engineering controls	General ventilation normally adequate.
Personal protective equipment	
Eye / face protection	Not normally required when used as directed. Emergency responders should wear full eye and face protection.
Hand protection	Not normally required. Emergency responders should wear impermeable gloves.
Skin and body protection	As required by employer code.
Respiratory protection	Not normally required.
General hygiene considerations	Washing with soap and water after use is recommended as good hygienic practice to prevent possible eye irritation from hand contact.

9. Physical and Chemical Properties

Appearance	Tablet
Color	Red
Form	Solid.
Odor	Berry
Odor threshold	Not available
Physical state	Solid
pH	Not applicable
Freezing point	Not available
Boiling point	Not available
Pour point	Not available
Evaporation rate	Not available
Flash point	Not available
Auto-ignition temperature	Not available
Flammability limits in air, lower, % by volume	Not applicable
Flammability limits in air, upper, % by volume	Not applicable
Vapor pressure	Not available

Vapor density	Not available
Specific gravity	Not available
Octanol/water coefficient	Not available
Solubility (H2O)	Soluble

10. Stability and Reactivity

Reactivity	None known.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Chemical stability	Stable under recommended storage conditions.
Conditions to avoid	Do not mix with other chemicals.
Incompatible materials	Oxidizers.
Hazardous decomposition products	May include and are not limited to: Oxides of carbon. Oxides of nitrogen. Oxides of sulphur. Oxides of sodium.

11. Toxicological Information

Component analysis - LC50

Ingredient(s)	LC50
Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	Not available
Benzocaine	Not available
Dextromethorphan hydrobromide	Not available

Component analysis - Oral LD50

Ingredient(s)	LD50
Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	29700 mg/kg rat
Benzocaine	1150 mg/kg rabbit; 3042 mg/kg rat
Dextromethorphan hydrobromide	Not available

Effects of acute exposure

Eye	There is no known adverse effect from exposure to the recommended use of this product.
Skin	There is no known adverse effect from exposure to the recommended use of this product.
Inhalation	There is no known adverse effect from exposure to the recommended use of this product.
Ingestion	There is no known adverse effect from exposure to the recommended use of this product.

Sensitization The finished product is not expected to have chronic health effects.

Chronic effects The finished product is not expected to have chronic health effects.

Carcinogenicity The finished product is not expected to have chronic health effects.

ACGIH - Threshold Limit Values - Carcinogens

Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	A4 - Not Classifiable as a Human Carcinogen
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Mutagenicity The finished product is not expected to have chronic health effects.

Reproductive effects The finished product is not expected to have chronic health effects.

Teratogenicity The finished product is not expected to have chronic health effects.

Name of Toxicologically Synergistic Products Not available

12. Ecological Information

Ecotoxicity See below

Ecotoxicity - Freshwater Fish - Acute Toxicity Data

Benzocaine	94-09-7	96 Hr LC50 Pimephales promelas: 34.6-36.1 mg/L [flow-through]; 96 Hr LC50 Pimephales promelas: 24.9-26.9 mg/L [static]; 96 Hr LC50 Lepomis macrochirus: 7.48-11.3 mg/L [static]; 96 Hr LC50 Cyprinus carpio: 17.9-20.1 mg/L [static]; 96 Hr LC50 Oncorhynchus mykiss: 5.92-9.76 mg/L [static]
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Persistence / degradability Not available

Bioaccumulation / accumulation Not available

Mobility in environmental media	Not available
Environmental effects	Not available
Aquatic toxicity	Not available
Partition coefficient	Not available
Chemical fate information	Not available

13. Disposal Considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Do not flush to surface water or sanitary sewer system.
Waste from residues / unused products	Not available
Contaminated packaging	Not available

14. Transport Information

UN/ID N.o. Not applicable

U.S. Department of Transportation (DOT): Classification: Not regulated

Proper shipping name	Not applicable
U.S. DOT Hazard Class	Not applicable
Subsidiary Risk	Not applicable
Packing group	Not applicable
DOT RQ (lbs)	Not applicable
ERG NO	Not applicable

Transportation of Dangerous Goods (TDG - Canada): Classification: Not regulated

Proper shipping name	Not applicable
Status	Not applicable
Packing group	Not applicable

IMDG (Marine Transport): Classification: Not regulated

Proper shipping name	Not applicable
Class	Not applicable
Subsidiary Risk	Not applicable
Packing group	Not applicable
IMDG Page	Not applicable
Marine pollutant	Not applicable
EMS	Not applicable
MFAG	Not applicable
Maximum Quantity	Not applicable

IATA/ICAO (Air): Classification: Not regulated

Proper shipping name	Not applicable
Class	Not applicable
Subsidiary Risk:	Not applicable
Packing group	Not applicable
Maximum Quantity	Not applicable

15. Regulatory Information

Occupational Safety and Health Administration (OSHA)

29 CFR 1910.1200 hazardous chemical No

US Federal regulations

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

All components of this product are either on the Toxic Substances Control Act list (TSCA) or exempt.

Product Registration: Registered with FDA

CERCLA (Superfund) reportable quantity

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance No

Section 311 hazardous chemical No

Clean Air Act (CAA) Not available

Clean Water Act (CWA) Not available

State regulations

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

U.S. - Massachusetts - Right To Know List

Alpha-D-Glucopyranoside, 57-50-1 Present (dust)
beta-D-fructofuranosyl

U.S. - Minnesota - Hazardous Substance List

Alpha-D-Glucopyranoside, 57-50-1 Present (dust)
beta-D-fructofuranosyl

U.S. - Pennsylvania - RTK (Right to Know) List

Alpha-D-Glucopyranoside, 57-50-1 Present
beta-D-fructofuranosyl

U.S. - Rhode Island - Hazardous Substance List

Alpha-D-Glucopyranoside, 57-50-1 Toxic
beta-D-fructofuranosyl

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other Information

Disclaimer	This product should only be used as directed on the label and for the purpose intended. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.
Further information	CEPACOL® Sore Throat & Cough Lozenges - Mixed Berry - 0354566 v2.0
Issue date	25-Jun-2012
Effective date	15-Jun-2012
Prepared by	Reckitt Benckiser Regulatory Department 800-333-3899
Other information	For an updated MSDS, please contact the supplier/manufacturer listed on the first page of the document.