

1. F	Product and Company Identification		
Product Name	CEPACOL® Maximum Strength Sore Throat Lozenges - Cherry		
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	Health / 1		
HMIS/NFPA			
Severe 4	Flammability 0		
Serious 3	Physical Hazard 0		
Moderate 2	Physical Hazard 0		
Slight 1 Minimal 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.		
	Stop use and ask a doctor of dentist if: sore mouth symptoms do not improve in 7 days		
	irritation, pain or redness persists or worsens		
	swelling develops		
	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.		
0'	There are no hazards associated with this product in normal use.		
Signs and symptoms OSHA Regulatory Status	This product is NOT known to be a "Hazardous Chemical" as defined by the OSHA		

<b>3. Con</b>	nposition / Information	on Ingredients	
Ingredient(s)		CAS #	Percent
Alpha-D-Glucopyranoside, beta-D-fruct	ofuranosyl	57-50-1	40 - 60
Benzocaine		94-09-7	0.1 - 1
L-Menthol		2216-51-5	0.1 - 1
	4. First Aid Meas	ures	
First aid procedures			
Eye contact	Immediately flush eyes with plenty of	of water for at least 15 minutes.	Get medical attentic
Skin contact	Wash with soap and water. Get med		
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, g oxygen. Get immediate medical attention.		
Ingestion	Not applicable. Get medical attentio	n immediately if adverse effects	are felt.
Notes to physician	Symptoms may be delayed.		
General advice	If you feel unwell, seek medical advi medical personnel are aware of the themselves. Show this safety data s of children.	material(s) involved, and take p	recautions to protect
	5. Fire Fighting Mea	asures	
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			
Sensitivity to static discharge	Not available		
	6. Accidental Release	Measures	
Personal precautions	Keep unnecessary personnel away.	Do not touch or walk through s	oilled material.
Environmental precautions	Do not discharge into lakes, stream	s, ponds or public waters.	
Methods for containment	Prevent entry into waterways, sewer	rs, basements or confined areas	5.
Methods for cleaning up	Pick up and discard.		
	7. Handling and St	orage	
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 i 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 Keep out of reach of children.	<sup>c</sup> )(20-25°C).	

Exposure limits		
Ingredient(s)	Exposure Limits	
Alpha-D-Glucopyranoside, beta-D-fruct	ofuranosyl ACGIH-TLV	
	TWA: 10 mg/m3	
	OSHA-PEL	
	TWA: 15 mg/m3	
Benzocaine	ACGIH-TLV	
	Not established	
	OSHA-PEL	
	Not established	
L-Menthol	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	Cherry
Odor threshold	Not available
Physical state	Solid
рН	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

Possibility of hazardous reactions	Н
Chemical stability	S
Conditions to avoid	D
Incompatible materials	С
Hazardous decomposition products	Ν

Hazardous polymerization does not occur. Stable under recommended storage conditions. Do not mix with other chemicals. Oxidizers. 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	
L-Menthol		Not available	
Component analysis - Oral LD	50		
Ingredient(s)		LD50	
Alpha-D-Glucopyranoside, beta-	D-fructofuranosyl	29700 mg/kg rat	
Benzocaine		1150 mg/kg rabbit; 3042 mg/kg rat	
L-Menthol		Not available	
Effects of acute exposure			
Еуе	There is r product.	There is no known adverse effect from exposure to the recommended use of this product.	
Skin	There is r product.	There is no known adverse effect from exposure to the recommended use of this product.	
Inhalation	There is r product.	There is no known adverse effect from exposure to the recommended use of this product.	
Ingestion	There is r product.	There is no known adverse effect from exposure to the recommended use of this product.	
Sensitization	The finish	The finished product is not expected to have chronic health effects.	
Chronic effects	The finish	The finished product is not expected to have chronic health effects.	
Carcinogenicity	The finish	The finished product is not expected to have chronic health effects.	
ACGIH - Threshold Limit Valu	ues - Carcinogens		
Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	A4 - Not Classifiable as a Human Carcinogen	
Mutagenicity	The finish	The finished product is not expected to have chronic health effects.	
Reproductive effects	The finish	The finished product is not expected to have chronic health effects.	
Teratogenicity	The finish	The finished product is not expected to have chronic health effects.	
Name of Toxicologically Syne Products	rgistic Not availa	able	

## **12. Ecological Information**

Ecotoxicity	See below	
Ecotoxicity - Freshwater Fish -	Acute Toxicity Data	I
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]
L-Menthol	2216-51-5	96 Hr LC50 Pimephales promelas: 18.9 mg/L [flow-through]
Persistence / degradability	Not available	e
<b>Bioaccumulation / accumulation</b>	Not available	e
Mobility in environmental media	Not available	e
Environmental effects	Not available	e
Aquatic toxicity	Not available	e
Partition coefficient	Not available	e
Chemical fate information	Not available	e

## **13. Disposal Considerations**

**Disposal instructions** 

Dispose in accordance with all applicable regulations. Do not flush to surface water or sanitary sewer system. Not available

Waste from residues / unused products Contaminated packaging

14. Transport Information

#### UN/ID N.o. Not applicable

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

Not available

Proper shipping name	Not applicable
U.S. DOT Hazard Class	Not applicable
Subsidiary Risk	Not applicable
Packing group	Not applicable
DOT RQ (lbs) ERG NO	Not applicable 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 A	dministratio	on (OSHA)	
29 CFR 1910.1200 hazardous chemical	us 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 q	uantity		
None			
Superfund Amendments and Real	uthorization	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 chemi	cal 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 K	now List		
beta-D-fructofuranosyl	57-50-1	Present (dust)	
U.S Minnesota - Hazardous Sub	stance List		
Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	Present (dust)	
U.S Pennsylvania - RTK (Right t	o Know) List		
beta-D-fructofuranosyl	57-50-1	Present	
U.S Rhode Island - Hazardous S	Substance Lis	st	
Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	Toxic	
Inventory status			
Country(s) or region	Invento	ry name On inventory (yes/no)*	
United States & Puerto Rico		ubstances Control Act (TSCA) Inventory Yes	
		uct comply with the inventory requirements administered by the governing country(s)	

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® Maximum Strength Sore Throat Lozenges - Cherry - 0354567v3.0
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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.