



SAFETY DATA SHEET

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1. IDENTIFICATION

Product Identifier

Material Name: Creomulsion For Children Soothing Cough Syrup

Other means of identification Creomulsion For Children Soothing Cough Syrup
(NDC 70893-0011-1)

Synonym(s) Not available

Relevant Identified Uses and restrictions

Recommended use Pharmaceutical product that temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold (cough suppressant).

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised

Manufacturer/Importer/Supplier/Distributor information

Manufactured by: Woodfield Pharmaceutical, LLC
10863 Rockley Rd
Houston, TX 77099 USA
US Information (normal business hours): +1-281-530-3077
Email Address: sds@wdprx.com
Website: www.woodfieldpharma.com

Manufactured for: Socius Care, LLC
3939 Royal Dr. NW Suite 230
Kennesaw, GA 30144
US Information (normal business hours): 1+404-566-8896
Website: www.creomulsion.com

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2. HAZARD(S) IDENTIFICATION

Classification of the Material

Classified hazards: Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label Elements

Signal Word Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.
Hazard Statements

Hazard(s) not otherwise classified (HNOC) Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Note This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Characterization: Mixtures

Description: Mixture of product components

Chemical name	Common name and synonyms	CAS number	%
Dextromethorphan Hydrobromide	3-Methoxy-17-methyl-9alpha,13alpha,14alpha-morphinan hydrobromide monohydrate Dextromethorphan Hydrobromide	6700-34-1	0.1
Citric Acid Anhydrous	1,2,3-Propanetricarboxylic acid, 2-hydroxy- 2-Hydroxy-1,2,3-propanetricarboxylic acid 2-Hydroxypropanetricarboxylic acid 2-Hydroxytricarballic acid 3-Carboxy-3-hydroxypentane-1,5-dioic acid Anhydrous citric acid Citric acid	77-92-9	*

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Corn Syrup Solids	Corn syrup Glucose syrup Hydrolyzed starch syrups	8029-43-4	*
FD&C Red No. 40	FD&C RED NO. 40	25956-17-6	*
Potassium Sorbate	2,4-Hexadienoic acid potassium salt, (E,E)- 2,4-Hexadienoic acid, potassium salt, (E,E)- Potassium (E,E)-2,4-hexadienoate Potassium 2,4-hexadienoate, (E,E)- Potassium sorbate	24634-61-5	*
Sodium Benzoate	Benzoic acid, sodium salt	532-32-1	*
Sucrose	(alpha-D-Glucosido)-beta-D- fructofuranoside alpha-D-Glucopyranoside, beta-D- fructofuranosyl- alpha-D-Glucopyranosyl beta-D- fructofuranoside beta-D-Fructofuranosyl alpha-D- glucopyranoside D-Sucrose Fructofuranoside, alpha-D-glucopyranosyl, beta-D Glucopyranoside, beta-D-fructofuranosyl, alpha-D Granulated sugar Sugar	57-50-1	*
Caramel Liquid	Caramel Liquid S.S. A.P.	NOT ASSIGNED	*
Cherry Flavor	Cherry Flavor AF159522, Art.	NOT ASSIGNED	*
Menthol	2-Isopropyl-5-methylcyclohexanol 5-Methyl-2-(1-methylethyl)cyclohexanol Mentholum Menthyl alcohol p-Menthan-3-ol	1490-04-6	*

Additional Information *Proprietary. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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4. FIRST-AID MEASURES

Description of First Aid Measures

Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Consult a physician.
Eye contact	Flush with water while holding eyelids open for at least 15 minutes. Consult a physician.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Call a physician or poison control center immediately.

Most important symptoms/effects, both acute and delayed

Nervousness, dizziness, or sleeplessness.

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	Extinguish fires with CO ₂ , extinguishing powder, foam, or water.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Formation of hazardous gases is possible during heating or fire.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Methods and materials for containment and cleaning up

Measures for Cleaning/Collecting:

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Environmental precautions

Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground. Place waste in an appropriately labeled, sealed container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.

Conditions for safe storage, Including any Incompatibilities

Storage Conditions:

Store as directed by product packaging.

Specific end use(s):

Pharmaceutical drug product

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits

Component	CAS Number	OSHA PEL LIMITS	ACGHI TLV LIMITS	OTHER LIMITS
Dextromethorphan Hydrobromide	6700-34-1	Not Indicated	Not Indicated	Not Indicated
Citric Acid Anhydrous	77-92-9	Not Indicated	Not Indicated	Not Indicated
Corn Syrup Solids	8029-43-4	Not Indicated	Not Indicated	Not Indicated
FD&C Red No. 40	25956-17-6	Not Indicated	Not Indicated	Not Indicated
Potassium Sorbate	24634-61-5	Not Indicated	Not Indicated	Not Indicated
Sodium Benzoate	532-32-1	Not Indicated	Not Indicated	Not Indicated
Sucrose	57-50-1	Not Indicated	Not Indicated	Not Indicated
Caramel Liquid	NOT ASSIGNED	Not Indicated	Not Indicated	Not Indicated
Cherry Flavor	NOT ASSIGNED	Not Indicated	Not Indicated	Not Indicated
Menthol	1490-04-6	Not Indicated	Not Indicated	Not Indicated

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection: Wear approved safety glasses with side shields if eye contact is possible.

Hand protection: The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards: Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations: When using, do not eat, drink or smoke. Wash hands after handling and before eating. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Physical state: Viscous liquid Color: medium red
Flammability	This product is non-flammable
Odor	cherry
Odor threshold	Not available
Vapor pressure	Not available
Vapor density	Not available
pH	3.0 – 3.5
Relative density	1.273 - 1.294
Melting/freezing point	Not available
Solubility(ies)	Not available
Initial boiling point and boiling range	Not available
Flash point	Not available
Evaporation rate	Not available
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	30 - 160 cps

10. STABILITY AND REACTIVITY

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Other	
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	No data available.

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11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

- General Information:** The information included in this section describes the potential hazards of the individual ingredients.
- Short Term:** May cause eye irritation (based on components).
- Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on overexposure like discomfort and gastrointestinal disturbances but symptoms are reversible and usually disappear when exposure stops (based on components).
- Known Clinical Effects:** Nervousness, dizziness, or sleeplessness may occur.

No chemical component is listed in the NTP Report on Carcinogens or has been found to be a potential carcinogen in the IARC Monographs or found to be a potential carcinogen by OSHA.

Toxicity:	Species	End Point	Route	Dose
Citric Acid Anhydrous	mouse	LD50	intraperitoneal	903mg/kg
	mouse	LD50	intravenous	42mg/kg
	mouse	LD50	oral	5040mg/kg
	mouse	LD50	subcutaneous	2700mg/kg
	rabbit	LD50	intravenous	330mg/kg
	rabbit	LDLo	oral	7gm/kg
	rat	LD50	intraperitoneal	290mg/kg
	rat	LD50	oral	3gm/kg
	rat	LD50	subcutaneous	5500mg/kg
FD&C Red No. 40	dog	LD50	oral	> 5gm/k
	rabbit	LD50	skin	> 10gm/kg
	rat	LD50	oral	> 10gm/kg
	dog	LD50	oral	2gm/kg
Sodium Benzoate	frog	LDLo	subcutaneous	100mg/kg
	guinea pig	LDLo	intraperitoneal	1400mg/kg
	guinea pig	LDLo	subcutaneous	1gm/kg
	mouse	LD50	intramuscular	2306mg/kg
	mouse	LD50	intravenous	1440mg/kg
	mouse	LD50	oral	1600mg/kg
	rabbit	LD50	oral	2gm/kg
	rabbit	LD50	subcutaneous	2gm/kg
	rat	LD50	intravenous	1714mg/kg
	rat	LD50	oral	4070mg/kg
	rat	LD50	subcutaneous	2gm/kg
	Sucrose	domestic animals - goat/sheep	LDLo	oral
Dextromethorphan Hydrobromide				no data available
Corn Syrup Solids				no data available

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Potassium Sorbate	no data available
Caramel Liquid	no data available
Cherry Flavor	no data available
Menthol	no data available

12. ECOLOGICAL INFORMATION

Not available.

13. DISPOSAL CONSIDERATIONS

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. TRANSPORT INFORMATION

DOT	Not regulated as a dangerous good.
IATA	Not regulated as a dangerous good.
IMDG	Not regulated as a dangerous good.

15. REGULATORY INFORMATION

US federal regulations	
TSCA Section 12(b) Export Notification (40 CFR 707, Subpart D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
SARA 304 Emergency release notification	Not regulated.

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16. OTHER INFORMATION

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Revision Information New SDS.

References Creomulsion For Children Soothing Cough Syrup
FDA Substance Registration System
TOXNET Toxicology Data Network
WDPrx Material components SDS

Disclaimer The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Key/Legend CAS = Chemical Abstract Service; CFR = Code of Federal Regulations; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limits; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; LD50 = Lethal Dose Fifty, a calculated dose that is expected to cause death in 50% of a given experimental animal population; LDLO = Lethal Dose Low, Lowest dose of a substance reported to have caused death in humans or animals; TDLO = Total Dose Low, lowest known dose of a substance that has produced any toxic, carcinogenic effects; DOT = Department of Transportation; IATA = International Air Transport Association; IMDG = International Maritime Dangerous Goods; TSCA = Toxic Substances Control Act; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; SARA = Superfund Amendments and Reauthorization Act.