SAFETY DATA SHEET

1. IDENTIFICATION

Product Identifier

Material Name: Guaifenesin Liquid USP

Other means of identification Guaifenesin Liquid USP 100 mg/5 mL
NDC 58657-509-16 (473 mL)

Synonym(s) Not available

Relevant Identified Uses and restrictions

Recommended use Pharmaceutical product that helps loosen phlegm (mucus) and thin bronchial secretions (expectorant).

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.wdprx.com

Distributed by:
Method Pharmaceuticals, LLC
2000 East Lamar Blvd. Suite 600
Arlington, TX 76006
US Information toll free: +1-877-250-3427
Website: http://methodpharm.com

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

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

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	%
Guaifenesin	(+-)-3-(o-Methoxyphenoxy)-1,2-propanediol 1,2,3-Propanetriol, ether with 2-methoxyphenol 1,2-Dihydroxy-3-(2-methoxyphenoxy)propane 1,2-Propanediol, 3-(2-methoxyphenoxy)- 1,2-Propanediol, 3-(2-methoxyphenoxy)- (+-)- 1,2-Propanediol, 3-(o-methoxyphenoxy)- 3-(2-Methoxyphenoxy)-1,2-propanediol	93-14-1	2.0
Citric Acid Anhydrous	1,2,3-Propanetricarboxylic acid, 2-hydroxy- 2-Hydroxy-1,2,3-propanetricarboxylic acid 2-Hydroxypropanetricarboxylic acid 2-Hydroxytricarballylic acid	77-92-9	*

	3-Carboxy-3-hydroxypentane-1,5-dioic acid Anhydrous citric acid Citric acid		
Sodium Citrate Dihydrate	Citric acid, trisodium salt, dihydrate Natrum citricum Trisodium citrate dihydrate	6132-04-3	*
Sodium Saccharin	1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt, dihydrate 1,2-Benzisothiazolin-3-one 1,1-dioxide sodium salt dihydrate Saccharin sodium Saccharin sodium dihydrate Saccharin soluble dihydrate Sodium o-benzosulfamide, dihydrate Sodium saccharin dihydrate Sucaryl	6155-57-3	*
Propylene Glycol	1,2-Propanediol	57-55-6	*
Sorbitol Solution	(-)-Sorbitol D-(-)-Sorbitol D-1,2,3,4,5,6-Hexanehexol D-Glucitol D-Sorbite D-Sorbitol D-Sorbol Glucitol Hexahydric alcohol L-Gulitol Neosorb Neosorb 20/60DC Neosorb 70/02 Neosorb 70/70 Neosorb P 20/60 Neosorb P 60	50-70-4	*
Glycerin	1,2,3-Propanetriol Glycerin, anhydrous Glycerine Glycyl alcohol Trihydroxypropane	56-81-5	*
Cherry Flavor	Cherry Flavor #213 CD44	NOT ASSIGNED	*
Additional Information	*Proprietary. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.		

4. FIRST-AID MEASURES

Description of First Aid Measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Take off immediately all contaminated clothing. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. If eye irritation persists: Get medical advice/attention.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, both acute and delayed

Possible allergic reaction if ingested or in contact with skin. If ingested in overdose quantities a range of symptoms may be present themselves which may include, but are not limited to any of the following: sedation, dryness of mouth, nose and throat, thickening of bronchial secretions, dizziness, urticaria, drug rash, photosensitivity, pruritus, hypotension, hypertension, cardiac arrhythmias, palpitation, disturbed coordination, tremor, irritability, insomnia, visual disturbances, weakness, nervousness, convulsions, headache, euphoria, dysphoria, difficult or frequent urination, epigastric discomfort, anorexia, nausea, vomiting, diarrhea, constipation, tightness of chest, wheezing, shortness of breath, hemolytic anemia, thrombocytopenia, and agranulocytosis.

Indication of the Immediate Medical Attention and Special Treatment Needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

General information

Take off all contaminated clothing immediately. In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	Extinguish fires with CO2, 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.

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 prolong exposure, contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits

Component	CAS Number	OSHA PEL LIMITS	ACGHI TLV LIMITS	OTHER LIMITS
Guaifenesin	93-14-1	Not Indicated	Not Indicated	Not Indicated
Citric Acid Anhydrous	77-92-9	Not Indicated	Not Indicated	Not Indicated
Sodium Citrate Dihydrate	6132-04-3	Not Indicated	Not Indicated	Not Indicated
Sodium Saccharin	6155-57-3	Not Indicated	Not Indicated	Not Indicated
Propylene Glycol	57-55-6	Not Indicated	Not Indicated	Not Indicated
Sorbitol Solution	50-70-4	Not Indicated	Not Indicated	Not Indicated
Glycerin	56-81-5	15 mg/m3 (total) 5 mg/m3 (resp.)	Not Indicated	Not Indicated
Cherry Flavor	NOT ASSIGNED	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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Physical state: Liquid Color: colorless
Flammability	This product is non-flammable
Odor	Cherry
Odor threshold	Not available
Vapor pressure	Not available
Vapor density	Not available
pH	3.0 - 6.0
Relative density	1.0300 - 1.2800
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	1.0 – 20.0 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.

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 hypersensitivity to any of the ingredients. (based on components).

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on overexposure. Toxic doses may result in CNS stimulation, tachycardia, hypertension, and cardia arrhythmias. Toxic doses will cause drowsiness, ataxia, nystagmus, opisthotonos, and convulsive seizures.

Known Clinical Effects: None identified.

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
Guaifenesin	dog	LD50	Intravenous	335mg/kg
	mouse	LD50	intramuscular	2210mg/kg
	mouse	LD50	intraperitoneal	495mg/kg
	mouse	LD50	intravenous	400mg/kg
	mouse	LD50	oral	690mg/kg
	mouse	LD50	subcutaneous	800mg/kg
	rabbit	LD50	oral	2553mg/kg
	rat	LD50	intramuscular	4000mg/kg

	rat	LD50	intraperitoneal	1000mg/kg
	rat	LD50	intravenous	360mg/kg
	rat	LD50	oral	1510mg/kg
	rat	LD50	subcutaneous	2550mg/kg
Propylene Glycol	chicken	LDLo	intravenous	27gm/kg
	child	TDLo	oral	79gm/kg
	dog	LD50	intravenous	26gm/kg
	dog	LD50	oral	22gm/kg
	guinea pig	LD50	oral	18350mg/kg
	guinea pig	LDLo	subcutaneous	15500mg/kg
	infant	TDLo	parenteral	10gm/kg
	mouse	LD50	intraperitoneal	9718mg/kg
	mouse	LD50	intravenous	6630mg/kg
	mouse	LD50	oral	22gm/kg
	mouse	LD50	subcutaneous	17370mg/kg
	quail	LD50	oral	> 2080mg/kg
	rabbit	LD50	intravenous	6500mg/kg
	rabbit	LD50	oral	18500mg/kg
	rabbit	LD50	skin	20800mg/kg
	rabbit	LDLo	intramuscular	6300mg/kg
	rat	LD50	intramuscular	14gm/kg
	rat	LD50	intraperitoneal	6660mg/kg
	rat	LD50	intravenous	6423mg/kg
	rat	LD50	oral	20gm/kg
	rat	LD50	subcutaneous	22500mg/kg
Sorbitol Solution	mouse	LD50	intraperitoneal	15gm/kg
	mouse	LD50	intravenous	9480mg/kg
	mouse	LD50	oral	17800mg/kg
	mouse	LD50	subcutaneous	24gm/kg
	rat	LD50	intravenous	7100mg/kg
	rat	LD50	oral	15900mg/kg
	rat	LD50	subcutaneous	29600mg/kg
	women	TDLo	oral	1700mg/kg
Glycerin	guinea pig	LD50	oral	7750mg/kg
	human	TDLo	oral	1428mg/kg
	mouse	LD50	intraperitoneal	8700mg/kg
	mouse	LD50	intravenous	4250mg/kg
	mouse	LD50	oral	4090mg/kg
	mouse	LD50	subcutaneous	91mg/kg
	rabbit	LD50	intravenous	53gm/kg
	rabbit	LD50	oral	27gm/kg
	rabbit	LD50	skin	> 10gm/kg
	rat	LC50	inhalation	> 570mg/m3
	rat	LD50	intraperitoneal	4420mg/kg
	rat	LD50	intravenous	5566mg/kg
	rat	LD50	oral	12600mg/kg
	rat	LD50	subcutaneous	100mg/kg
	rat	LDLo	intramuscular	10mg/kg
Sodium Saccharin	dog	LDLo	intravenous	2500mg/kg
	mouse	LD50	intraperitoneal	17500mg/kg
	rabbit	LDLo	oral	5gm/kg
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
Sodium Citrate Dihydrate		no data available		
Cherry Flavor		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.
DEA Drug Enforcement Administration	Regulated.

16. OTHER INFORMATION

Revision date	04/26/2016
Version #	1.0
Revision Information	New SDS.
References	Label product insert FDA Substance Registration System TOXNET Toxicology Data Network WDP 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; LDL0 = Lethal Dose Low, Lowest dose of a substance reported to have caused death in humans or animals; TDL0 = 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.