

SAFETY DATA SHEET

1. <u>Identification</u>

Product Identifier: Guaifenesin Oral Solution

Synonyms: Guaicol glycerol ether

National Drug Code (NDC): 50383-063-06

50383-063-07 50383-063-11 50383-063-12 50383-063-17 50383-063-18

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.

1925 West Field Court, Suite 300 Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. <u>Hazard(s) Identification</u>

Physical Hazards: Combustible liquid Category 4

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: Warning.

Hazard Statement(s): H227 Combustible liquid.

Precautionary Statement(s): P210 Keep away from flames and hot surfaces. No

smoking.

P280 Wear protective gloves/eye protection/ face

protection.

P370 In case of fire: Use water, carbon dioxide, dry

chemical or foam as necessary to extinguish.

P378

P403 Store in a well-ventilated place. Keep cool.

+ P235

P501 Dispose of contents/container in accordance

with local/regional/national/international

regulations.



Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: None.

Composition/Information on Ingredients 3.

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Guaifenesin	93-14-1	Guaicol glycerol ether	C ₁₀ H ₁₄ O ₄	198.22	2%

^{*}The f Menth

4.

	rtificial Cherry & Vanilla Flavor, Aspartame, Hypromellose, e, and Purified Water. Citric Acid may be used to adjust pH.
First Aid Measures	
Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Solution is an over the counter (OTC) drug product and

Solution is an over the counter (OTC) drug product and is intended for human consumption. Solution is not

considered hazardous under normal conditions.



None.

Medical Conditions Aggravated

by Exposure:

Other Health Warnings: Ask a doctor before use if you have: cough that occurs

with too much phlegm (mucus). A persistent or chronic cough such as occurs with smoking, asthma, chronic

bronchitis, or emphysema.

If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control

Center right away.

Notes to Physician: Not available.

5. <u>Firefighting Measures</u>

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as

necessary.

Unsuitable Extinguishing Media: With small quantities use carbon dioxide extinguisher.

For large fires use ample quantities of water with dry

chemicals or foam as necessary.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Not determined.

Other Specific Hazards: Not determined.

Special Protective Equipment/

Precautions for Firefighters: Wear self-contained breathing apparatus and full and

protective gear.

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in

Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Pick up in the most efficient manner. Soak up with

sawdust, sand oil dry or other absorbent material.

Environmental Precautions: No data available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product

insert information. Handle in accordance with good

industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities:

Store according to label and/or product insert

information. Store away from oxidizing agents and acids.



Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits		
Guaifenesin	Not established.		

Engineering Controls: Not required for the normal use of this product.

Engineering controls should be used as the primary

means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or

control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29

CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended.

Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in

the work area.

Hand Protection: Chemically compatible gloves are recommended. For

handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of

powdered latex gloves should be avoided due to the risk

of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable

garment when working with large quantities.

9. **Physical and Chemical Properties**

Physical State/Color: Clear viscous liquid.
Odor: Slight cherry odor.

Odor Threshold:

pH:

No data available.

Flash Point: >140°F.

Evaporation Rate: Same as water.
Flammability (solid, gas): No data available.
Flammability Limit - Lower: No data available.
Flammability Limit - Upper: No data available.
Vapor Pressure: No data available.

Vapor Density: >1.



Relative Density:

Solubility(ies):

No data available.

Very soluble in water.

Partition Coefficient

(n-octanol/water):No data available.Auto-Ignition Temperature:No data available.Decomposition Temperature:No data available.Viscosity:No data available.

10. Stability and Reactivity

Reactivity: Will not occur.

Chemical Stability: Stable under recommended storage conditions. Avoid

sources of ignition.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static

discharge, shock, or vibration): No data available.

Incompatible Materials: Strong oxidizer.

Hazardous Decomposition

Products: Does not undergo explosive decomposition.

11. <u>Toxicological Information</u>

Information on the Likely Routes of Exposure:

Inhalation:No data available.Ingestion:No data available.Skin Contact:No data available.Eye Contact:No data available.

Symptoms Related to the Physical,

Chemical and Toxicological

Characteristics: See Section 4. To the best of our knowledge, the

chemical, physical and toxicological properties have not

been thoroughly investigated.

Delayed and Immediate Effects of

Exposure: No data available.

No data available. Acute Toxicity - Oral: **Acute Toxicity – Dermal:** No data available. Acute Toxicity - Inhalation: No data available. Corrosivity: No data available. **Dermal Irritation:** No data available. **Eve Irritation:** No data available. Sensitization: No data available. Toxicokinetics/Metabolism: No data available. **Target Organ Effects:** No data available. **Reproductive Effects:** No data available. Carcinogenicity: No data available.



National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on

Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health

Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity:No data available.Aspiration Hazard:No data available.

12. Ecological Information

Ecotoxicity

Aquatic:
Terrestrial:
No data available.
Persistence and Degradability:
Bioaccumulative Potential:
Mobility in Soil:
Mobility in Environment:
Other Adverse Effects:
No data available.
No data available.
No data available.
No data available.

13. <u>Disposal Considerations</u>

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:
UN Proper Shipping Name:
Transport Hazard Class(es):
Packing Group:

Not applicable.
Not applicable.
Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport

Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous

Good (IMDG): Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act

(TSCA): Not listed.

CERCLA Hazardous Substance

and Reportable Quantity: Not listed.

SARA 313: Not listed. SARA 302: Not listed.



State Regulations

California Proposition 65: Not listed.

16. Other Information

NFPA Rating:

Health: 1 Flammability: 1 Reactivity: 0

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