

# Safety Data Sheet

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## 1. Identification of the substance/preparation and the company/undertaking

### GHS product identifier

Product name: Fluphenazine Hydrochloride Oral Solution USP (Concentrate)

### Other means of identification

Product code(s): **0121-0653-04**

UN-Number: NA

Synonyms: NA

### Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product indicated in the management of manifestations of psychotic disorders.

Uses advised against: Do not use except as prescribed.

### Supplier address/information

Pharmaceutical Associates, Inc.  
201 Delaware Street  
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

## 2. Hazards Identification

**Classification** This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

**Chemical family:** Mixture

**Statement of Hazard:** Product is not considered hazardous when used as prescribed.

### Additional Hazard Information

**Short term:** Increased mortality in elderly patients with dementia-related psychosis. Fluphenazine HCl Elixir is not approved for the treatment of dementia-related psychosis.

**Long term:** The possibility of liver damage, pigmentary retinopathy, lenticular and corneal deposits, and development of irreversible dyskinesia should be remembered when patients are on prolonged therapy.

**Known Clinical Effects:** The side effects most frequently reported are extrapyramidal symptoms.

**EU Indication of danger:** Not classified.

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## Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

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

Eyes:	Avoid contact with eyes.
Skin Contact:	Avoid skin contact.
Inhalation:	Not intended for inhalation.
Ingestion:	Generally safe at recommended doses. In case of overdose, seek medical attention immediately.
Storage:	There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.
Disposal:	Dispose of in accordance with applicable laws and regulations.

## 3. Composition/Information on ingredients

Chemical name	CAS-No	mg/mL or %v/v	Trade Secret
Fluphenazine Hydrochloride	146-56-5	5 mg/mL	
Alcohol 190 Proof	64-17-5	14% v/v	
	(200 Proof)		
Sodium Benzoate	532-32-1		X
Glycerin	56-81-5		X

## 4. First aid measures

### Description of necessary first-aid measures

#### Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel.

#### Skin contact:

Wash contaminated area thoroughly with soap and water. If irritation persists, contact medical personnel.

#### Inhalation:

Remove to fresh air and contact medical personnel.

#### Ingestion:

Over-dosage or accidental ingestion: Contact medical personnel or poison control center.

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**Most important symptoms/effects, acute and delayed**

Not available.

**Indication of immediate medical attention and special treatment needed, if necessary**

NA

Notes to Physician: NA

## 5. Fire-fighting measures

**Suitable extinguishing media:**

Use carbon dioxide, dry chemical or water spray.

**Specific hazards arising from the chemical**

May burn emitting oxides of chlorine, nitrogen and carbon.

**Explosion data:**

Not applicable

**Protective equipment and precautions for firefighters**

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.

**Environmental precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and materials for containment and cleaning up**

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures. Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

## 7. Handling and storage

**Precautions for safe handling**

Handling:

No special handling required for hazard control under conditions of normal product use.

**Conditions for safe storage, including any incompatibilities**

Storage:

No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products:

Not applicable.

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## 8. Exposure controls/personal protection

### Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Fluphenazine Hydrochloride	Not Available	Not Available	Not Available
Alcohol 190 proof	Not Available	1900 mg/m <sup>3</sup> TWA	Not Available
Sodium Benzoate	Not Available	Not Available	Not Available
Glycerin	10 mg/m <sup>3</sup> TWA	10 mg/m <sup>3</sup> TWA	Not Available

### Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

### Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Impervious gloves and protective clothing are recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures: Wash hands thoroughly after use.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state: Solution  
Odor: Slight  
Appearance: Clear colorless liquid  
Odor threshold: Not available

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Property	Values	Remarks/Method
pH	4.0 – 5.0	Current USP
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	1.1	Current USP
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

## Other information

VOC content (%): Alcohol 14% v/v

## 10. Stability and reactivity

**Reactivity** Stable at normal conditions

**Chemical stability** Stable at normal conditions

**Possibility of hazardous reactions** Stable at normal conditions

**Conditions to avoid** Keep away from heat and other sources of ignition, including electrostatic discharge.

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers

**Hazardous decomposition products** None known

## 11. Toxicological information

### Information on likely routes of exposure

#### Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Fluphenazine Hydrochloride	220 mg/kg Mouse	Not Available	Not Available
Alcohol	3632 mg/kg Mouse	Not Available	20000 ppm 10h Rat
Sodium Benzoate	2100 mg/kg Rat	Not Available	Not Available
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available

### Symptoms related to the physical, chemical and toxicological characteristics

No data available.

### Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: Germ cell mutagenicity (Drosophila)
- Carcinogenicity: Not carcinogenic
- Reproductive toxicity: May cause congenital malformation in the fetus. Suspected human reproductive toxicant.
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

### Numerical measures of toxicity – product

- No data available

## 12. Ecological information

### Ecotoxicity:

Environmental properties have not been thoroughly evaluated for this product. Releases to the environment should be avoided.

### Persistence and Degradability

No data available

### Bioaccumulation

No data available

### Other adverse effects:

No data available

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The following table includes data for the individual components.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Fluphenazine Hydrochloride	Not Available	Not Available	Not Available	Not Available
Alcohol	Not Available	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	484 mg/L 96 hr. Pimephales Promelas	Not Available	Not Available
Glycerin	Not Available	58.5 ppm 96 hr Trout	Not Available	Not Available

## 13. Disposal considerations

### Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

### Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

## 14. Transport information

### Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

## 15. Regulatory information

### International inventories

#### TSCA:

United States Toxic Substances Control Act 8(b) inventory not applicable for product. Fluphenazine Hydrochloride Alcohol, Sodium Benzoate, and Glycerin are listed.

#### EINECS:

Alcohol, Glycerin, Sodium Benzoate, and Fluphenazine Hydrochloride are listed on the inventory

#### U.S. Federal regulations:

Not listed as dangerous goods.

#### SARA 311/312 Hazard categories:

Not Applicable

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## Clean Water Act

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA No components are listed under CERCLA.**

## California Proposition 65:

This product contains Alcohol which is listed on Proposition 65.

## U.S. state Right-to-Know regulations

“X” designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Fluphenazine Hydrochloride	X		X		
Alcohol	X	X	X	X	X
Sodium Benzoate	X		X		
Glycerin	X	X	X	X	X

## U.S. EPA label information:

Not applicable

## 16. Other information

Prepared by: Pharmaceutical Associates Regulatory Affairs  
Issuing date: 03/11/2015  
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### General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of Safety Data Sheet**