

# Fluphenazine Decanoate Injection USP

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Fluphenazine Decanoate Injection USP  
Other means of Identification : 125 mg per 5 mL (1s) (NDC 55150-267-05)

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics Pharma LLC  
279 Princeton-Hightstown Road  
East Windsor, NJ 08520  
T 888-238-7880

#### 1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Acute Tox. 4 (Oral) H302  
Resp. Sens. 1 H334  
Skin Sens. 1 H317  
Lact. H362

Full text of hazard classes and H-statements : see section 16

#### 2.2. Label elements

##### GHS-US labeling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H302 - Harmful if swallowed  
H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H362 - May cause harm to breast-fed children

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P263 - Avoid contact during pregnancy/while nursing  
P264 - Wash thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P272 - Contaminated work clothing must not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P284 - [In case of inadequate ventilation] wear respiratory protection  
P301+P312 - If swallowed: Call a poison center/doctor if you feel unwell  
P302+P352 - If on skin: Wash with plenty of water  
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing  
P308+P313 - If exposed or concerned: Get medical advice/attention  
P330 - Rinse mouth  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention  
P342+P311 - If experiencing respiratory symptoms: Call a poison center/doctor  
P363 - Wash contaminated clothing before reuse  
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

#### 2.3. Other hazards

No additional information available

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### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/Information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Fats and Glyceridic oils, sesame	(CAS No) 8008-74-0	> 90	Not classified
Fluphenazine decanoate	(CAS No) 5002-47-1	1 - 5	Acute Tox. 2 (Oral), H300 Resp. Sens. 1, H334 Skin Sens. 1, H317 Lact., H362
Benzyl alcohol	(CAS No) 100-51-6	1 - 5	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312

Full text of hazard classes and H-statements : see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: If not breathing, give artificial respiration. Seek immediate medical attention.
First-aid measures after skin contact	: Wash skin with soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
First-aid measures after eye contact	: Flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
First-aid measures after ingestion	: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed by medical personnel.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/injuries after skin contact	: May cause an allergic skin reaction.
Symptoms/injuries after eye contact	: May cause eye irritation.
Symptoms/injuries after ingestion	: Harmful if swallowed.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray.
Unsuitable extinguishing media	: None.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
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### 5.3. Advice for firefighters

Protection during firefighting	: Firefighters should wear full protective gear.
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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special measures required.
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#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
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Methods for cleaning up : Absorb spill with inert material, then place in a chemical waste container. Dispose in accordance with federal, state and local requirements.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at controlled room temperature 20-25 C (68-77 F). Protect from light and excessive heat.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Fluphenazine decanoate (5002-47-1)

Not applicable

#### Benzyl alcohol (100-51-6)

AIHA	WEEL TWA (ppm)	10 ppm
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#### Fats and Glyceridic oils, sesame (8008-74-0)

Not applicable

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Use chemical resistant gloves to minimize skin contact.

Eye protection : Chemical splash goggles. Wear a face shield if a splash hazard exists.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Color	: Pale yellow
Odor	: No data available
Odor threshold	: No data available
pH	: 4.8 - 5.2
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Insoluble.
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available

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Explosive properties : No data available

Oxidizing properties : No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

Protect from freezing. Exposure to light may cause decomposition.

### 10.5. Incompatible materials

Not determined.

### 10.6. Hazardous decomposition products

Not determined.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

Fluphenazine Decanoate Injection USP	
ATE US (oral)	754.406 mg/kg body weight
Fluphenazine decanoate (5002-47-1)	
LD50 oral rat	19 mg/kg
ATE US (oral)	19 mg/kg body weight
Benzyl alcohol (100-51-6)	
LD50 oral rat	1230 mg/kg
LD50 dermal rabbit	2 g/kg
LC50 inhalation rat (mg/l)	8.8 mg/l/4h
ATE US (oral)	1230 mg/kg
ATE US (dermal)	2000 mg/kg
Fats and Glyceridic oils, sesame (8008-74-0)	
LD50 dermal rabbit	> 2 g/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : May cause harm to breast-fed children.

Specific target organ toxicity – single exposure : Not classified

Specific target organ toxicity – repeated exposure : Not classified

Aspiration hazard : Not classified

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Benzyl alcohol (100-51-6)	
LC50 fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

Benzyl alcohol (100-51-6)	
Log Pow	1.1

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Fats and Glyceridic oils, sesame (8008-74-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

#### 15.2. US State regulations

Benzyl alcohol (100-51-6)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	

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### SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Flam. Liq. 4	Flammable liquids Category 4
Lact.	Reproductive toxicity (Lact.)
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Sens. 1	Skin sensitization Category 1
H227	Combustible liquid
H300	Fatal if swallowed
H302	Harmful if swallowed
H312	Harmful in contact with skin
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H362	May cause harm to breast-fed children

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*