

Progesterone Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Progesterone Injection
Other means of identification : 10 mL multidose vials (NDC 55150-306-10)

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
279 Princeton Highstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Carc. 1B H350
Repr. 1B H360

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

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



GHS08

Signal word (GHS US) : Danger
Hazard statements (GHS US) : H350 - May cause cancer
H360 - May damage fertility or the unborn child
Precautionary statements (GHS US) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Name	Product identifier	%	GHS US classification
Benzyl alcohol	(CAS-No.) 100-51-6	10 - 15	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312
Progesterone	(CAS-No.) 57-83-0	1 - 5	Acute Tox. 4 (Oral), H302 Carc. 1B, H350 Repr. 1B, H360
Fats and Glyceridic oils, sesame	(CAS-No.) 8008-74-0	Balance	Not classified

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 inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.
- First-aid measures after skin contact : In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.
- First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
- First-aid measures after ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

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

- Symptoms/injuries after inhalation : Inhalation not likely under normal use conditions. May cause respiratory tract irritation.
- Symptoms/injuries after skin contact : May cause irritation.
- Symptoms/injuries after eye contact : May cause eye irritation.
- Symptoms/injuries after ingestion : May be 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 extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : Firefighters should wear full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : No special measures required.

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 : For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

6.4. Reference to other sections

No additional information available

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Benzyl alcohol (100-51-6)		
AIHA	WEEL TWA (ppm)	10 ppm
Fats and Glyceridic oils, sesame (8008-74-0)		
Not applicable		
Progesterone (57-83-0)		
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, impervious gloves.
Eye protection : Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.
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, oily
Color : Pale yellow to yellow
Odor : Odorless
Odor threshold : No data available
pH : No data available
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 : Soluble in water
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
Explosive properties : No data available
Oxidizing properties : No data available

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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

None.

10.5. Incompatible materials

Oxidizing agents.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

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

Progesterone (57-83-0)	
ATE US (oral)	500 mg/kg body weight

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : May cause cancer.

Progesterone (57-83-0)	
IARC group	2B - Possibly carcinogenic to humans
National Toxicology Program (NTP) Status	3 - Reasonably anticipated to be Human Carcinogen
In OSHA Hazard Communication Carcinogen list	Yes

Reproductive toxicity : May damage fertility or the unborn child.

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 applicable

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	
Progesterone (57-83-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State regulations

Progesterone (57-83-0)				
U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significant risk level (NSRL)
Yes	No	No	No	

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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Progesterone (57-83-0)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 1B	Carcinogenicity Category 1B
Flam. Liq. 4	Flammable liquids Category 4
Repr. 1B	Reproductive toxicity Category 1B
H227	Combustible liquid
H302	Harmful if swallowed
H312	Harmful in contact with skin
H350	May cause cancer
H360	May damage fertility or the unborn child

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.