

# Leuprolide Acetate Injection

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Leuprolide Acetate Injection  
Other means of identification : 14 mg per 2.8 mL multiple dose vial, NDC 55150-338-01

#### 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

Resp. Sens. 1 H334  
Skin Sens. 1 H317  
Repr. 1A 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) : H317 - May cause an allergic skin reaction  
H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled  
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.  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.  
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.  
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.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.  
P363 - Wash contaminated clothing before reuse.  
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

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### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	99.5	Not classified
Sodium hydroxide	(CAS-No.) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Benzyl alcohol	(CAS-No.) 100-51-6	< 1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332
Acetic acid	(CAS-No.) 64-19-7	< 1	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312
Sodium chloride	(CAS-No.) 7647-14-5	< 1	Not classified
Leuprolide Acetate	(CAS-No.) 74381-53-6	0.5	Acute Tox. 4 (Inhalation), H332 Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1A, H360

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.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.
- First-aid measures after ingestion : Go into open air and ventilate suspected area.

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

- Symptoms/effects after inhalation : May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
- Symptoms/effects after skin contact : May cause an allergic skin reaction.
- Symptoms/effects after eye contact : May cause eye irritation.
- Symptoms/effects 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 : Do not enter fire area without proper protective equipment, including respiratory protection.

### 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

#### 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 spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

### 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 prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

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

Storage conditions : Store at 20° to 25°C (68° to 77°F).

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) [1]	2 mg/m <sup>3</sup>
IDLH	IDLH	10 mg/m <sup>3</sup>
NIOSH	NIOSH REL (Ceiling)	2 mg/m <sup>3</sup>
Water (7732-18-5)		
Not applicable		
Benzyl alcohol (100-51-6)		
AIHA	WEEL TWA [ppm]	10 ppm
Leuprolide Acetate (74381-53-6)		
Not applicable		
Sodium chloride (7647-14-5)		
Not applicable		
Acetic acid (64-19-7)		
ACGIH	ACGIH OEL TWA [ppm]	10 ppm
ACGIH	ACGIH OEL STEL [ppm]	15 ppm
OSHA	OSHA PEL (TWA) [1]	25 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) [2]	10 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (TWA)	25 mg/m <sup>3</sup>
NIOSH	NIOSH REL TWA [ppm]	10 ppm
NIOSH	NIOSH REL (STEL)	37 mg/m <sup>3</sup>
NIOSH	NIOSH REL STEL [ppm]	15 ppm

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : No protection is ordinarily required under normal conditions of use.  
Eye protection : Wear safety glasses or goggles.  
Skin and body protection : Wear suitable working clothes.  
Respiratory protection : No protection is ordinarily required under normal conditions of use.

## SECTION 9: Physical and chemical properties

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

Physical state : Liquid

Appearance : Clear.

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Color	: Colorless
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	: completely soluble.
Partition coefficient n-octanol/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

### 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

Air contact.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

<b>Sodium hydroxide (1310-73-2)</b>	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg
<b>Water (7732-18-5)</b>	
LD50 oral rat	> 90 ml/kg
<b>Benzyl alcohol (100-51-6)</b>	
LD50 oral rat	1230 mg/kg
LD50 dermal rabbit	2 g/kg

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<b>Benzyl alcohol (100-51-6)</b>	
LC50 Inhalation - Rat	8.8 mg/l/4h
ATE US (oral)	1230 mg/kg body weight
ATE US (dermal)	2000 mg/kg body weight
ATE US (gases)	4500 ppmV/4h
ATE US (vapors)	8.8 mg/l/4h
ATE US (dust, mist)	1.5 mg/l/4h
<b>Leuprolide Acetate (74381-53-6)</b>	
ATE US (gases)	4500 ppmV/4h
ATE US (vapors)	11 mg/l/4h
ATE US (dust, mist)	1.5 mg/l/4h
<b>Sodium chloride (7647-14-5)</b>	
LD50 oral rat	3 g/kg
LD50 dermal rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation - Rat	> 42 g/m <sup>3</sup> (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg
<b>Acetic acid (64-19-7)</b>	
LD50 oral rat	3310 mg/kg
LD50 dermal rabbit	1060 mg/kg
LC50 Inhalation - Rat	11.4 mg/l/4h
ATE US (oral)	3310 mg/kg
ATE US (dermal)	1060 mg/kg
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: May cause an 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 damage fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

<b>Sodium hydroxide (1310-73-2)</b>	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
<b>Benzyl alcohol (100-51-6)</b>	
LC50 - Fish [1]	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [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])
<b>Sodium chloride (7647-14-5)</b>	
LC50 - Fish [1]	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
<b>Acetic acid (64-19-7)</b>	
LC50 - Fish [1]	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

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### Acetic acid (64-19-7)

LC50 - Fish [2]	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
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### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

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

Partition coefficient n-octanol/water (Log Pow)	1.1
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#### Sodium chloride (7647-14-5)

BCF - Fish [1]	(no bioaccumulation)
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#### Acetic acid (64-19-7)

Partition coefficient n-octanol/water (Log Pow)	-0.31 (at 20 °C)
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### 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

#### Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	1000 lb
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#### Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

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

Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### Sodium chloride (7647-14-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### Acetic acid (64-19-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	5000 lb
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### 15.2. US State regulations

#### Sodium hydroxide (1310-73-2)

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

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### 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

### Acetic acid (64-19-7)

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 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Repr. 1A	Reproductive toxicity Category 1A
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Sens. 1	Skin sensitization, Category 1
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H332	Harmful if inhaled
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
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.*