

Dexamethasone Sodium Phosphate Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Dexamethasone Sodium Phosphate Injection
Other means of identification : 4 mg /1 mL Single Dose Vials (contains preservative) NDC 55150-237-01
20 mg/5 mL Multiple Dose Vials NDC 55150-238-05
120 mg/30 mL Multiple Dose Vials NDC 55150-239-30
10 mg/1 mL Single Dose Vials NDC 55150-304-25
100 mg/10 mL Multiple Dose Vials NDC 55150-305-10

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

Skin Irrit. 2 H315
Eye Irrit. 2A H319
Repr. 2 H361

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) : Warning

Hazard statements (GHS US) : H315 - Causes skin irritation
H319 - Causes serious eye irritation
H361 - Suspected of damaging 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.
P264 - Wash hands, forearms and face thoroughly after handling.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it 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	Not classified
Sodium hydroxide	(CAS-No.) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Trisodium citrate	(CAS-No.) 68-04-2	< 1	Not classified
Citric acid monohydrate	(CAS-No.) 5949-29-1	< 1	Eye Irrit. 2A, H319
Sodium sulfite (4 mg/mL only)	(CAS-No.) 7757-83-7	< 1	Acute Tox. 4 (Oral), H302
Benzyl alcohol (except 10 mg/ 1 mL Single-Dose Vials)	(CAS-No.) 100-51-6	< 1	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312
Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy)-, disodium salt, (11.beta.,16.alpha.)-	(CAS-No.) 2392-39-4	0.4	Acute Tox. 4 (Oral), H302 Repr. 2, H361 STOT RE 2, H373

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 : Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

- Symptoms/injuries after inhalation : None anticipated during normal product use.
- Symptoms/injuries after skin contact : Causes skin irritation.
- Symptoms/injuries after eye contact : Causes serious 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 : During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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.

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6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
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.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store at 20° to 25°C (68° to 77°F).
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)		
Not applicable		
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
IDLH	US IDLH (mg/m ³)	10 mg/m ³
NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
Citric acid monohydrate (5949-29-1)		
Not applicable		
Sodium sulfite (7757-83-7)		
Not applicable		
Trisodium citrate (68-04-2)		
Not applicable		
Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy)-, disodium salt, (11.beta.,16.alpha.)- (2392-39-4)		
Not applicable		
Benzyl alcohol (100-51-6)		
AIHA	WEEL TWA (ppm)	10 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.
Color	: Colorless
Odor	: odorless
Odor threshold	: No data available
pH	: 7 – 8.5
Melting point	: No data available

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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
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

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg
Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg
Sodium sulfite (7757-83-7)	
LD50 oral rat	5680 mg/kg
LC50 inhalation rat (mg/l)	> 22 mg/l (Exposure time: 1 h)
ATE US (oral)	820 mg/kg body weight
Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy)-, disodium salt, (11.beta.,16.alpha.)- (2392-39-4)	
ATE US (oral)	500 mg/kg body weight
Benzyl alcohol (100-51-6)	
LD50 oral rat	1230 mg/kg

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Benzyl alcohol (100-51-6)	
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

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Sodium sulfite (7757-83-7)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Suspected of damaging 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

Sodium hydroxide (1310-73-2)	
LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

Trisodium citrate (68-04-2)	
LC50 fish 1	18000 – 32000 mg/l (Exposure time: 96 h - Species: Poecilia reticulata)
EC50 Daphnia 1	5600 – 10000 mg/l (Exposure time: 48 h - Species: Daphnia magna)

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

Sodium sulfite (7757-83-7)	
Partition coefficient n-octanol/water (Log Pow)	-4 (at 25 °C)

Benzyl alcohol (100-51-6)	
Partition coefficient n-octanol/water (Log Pow)	1.1

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

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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 a dangerous good as defined in transport regulations

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)

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

Sodium hydroxide (1310-73-2)

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

CERCLA RQ

1000 lb

Sodium sulfite (7757-83-7)

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

Trisodium citrate (68-04-2)

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

Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy)-, disodium salt, (11.beta.,16.alpha.)- (2392-39-4)

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

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

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

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
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H227	Combustible liquid
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation

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H318	Causes serious eye damage
H319	Causes serious eye irritation
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure

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.