**SECTION 1: Identification**

1.1. **Identification**

<table>
<thead>
<tr>
<th>Product name</th>
<th>Dexamethasone Sodium Phosphate Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other means of ident</td>
<td>4 mg/1 mL Single Dose Vials NDC 55150-237-01</td>
</tr>
<tr>
<td></td>
<td>20 mg/5 mL Multiple Dose Vials NDC 55150-238-05</td>
</tr>
<tr>
<td></td>
<td>120 mg/30 mL Multiple Dose Vials NDC 55150-239-30</td>
</tr>
</tbody>
</table>

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  
6 Wheelling Road  
Dayton, NJ 08810  
T 609-642-1136

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**

**Classification (GHS-US)**

| Skin Irrit. | H315 |
| Eye Irrit.  | H319 |
| Repr.       | H361 |

Full text of H-phrases: see section 16

2.2. **Label elements**

**GHS-US labeling**

<table>
<thead>
<tr>
<th>Hazard pictograms (GHS-US)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="GHS07" /></td>
<td><img src="image" alt="GHS08" /></td>
</tr>
</tbody>
</table>

**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 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
- 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 in accordance with local/regional/national/international regulations.

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. Substance
Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>(CAS No) 7732-18-5</td>
<td>&lt; 99</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>(CAS No) 1310-73-2</td>
<td>&lt; 1</td>
<td>Met. Corr. 1, H290</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1A, H314</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1, H318</td>
</tr>
<tr>
<td>Sodium sulfite</td>
<td>(CAS No) 7757-83-7</td>
<td>&lt; 1</td>
<td>Acute Tox. 4 (Oral), H302</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>(CAS No) 5949-29-1</td>
<td>&lt; 1</td>
<td>Eye Irrit. 2A, H319</td>
</tr>
<tr>
<td>Trisodium citrate</td>
<td>(CAS No) 68-04-2</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21- (phosphonooxy)-, disodium salt, (11.beta.,16.alpha.)-</td>
<td>(CAS No) 2392-39-4</td>
<td>0.4</td>
<td>Acute Tox. 4 (Oral), H302 Repr. 2, H361 STOT RE 2, H373</td>
</tr>
</tbody>
</table>

Full text of H-phares: 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.

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.

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

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td></td>
<td>ACGIH Ceiling (mg/m³)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSHA</td>
<td></td>
<td>OSHA PEL (TWA) (mg/m³)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IDLH</td>
<td></td>
<td>US IDLH (mg/m³)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NIOSH</td>
<td></td>
<td>NIOSH REL (ceiling) (mg/m³)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear.</td>
</tr>
<tr>
<td>Color</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>odorless</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7 - 8.5</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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Flammability (solid, gas) : No data available
Explosion limits : No data available
Explosive properties : No data available
Oxidizing properties : No data available
Vapor pressure : No data available
Relative density : No data available
Relative vapor density at 20 °C : No data available
Solubility : Soluble.
Log Pow : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
Vapor density at 20 °C : No data available
Solubility : 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 dermal rabbit 1350 mg/kg
ATE US (dermal) 1350.000 mg/kg

Sodium sulfite (7757-83-7)
LD50 oral rat 820 mg/kg
LC50 inhalation rat (mg/l) > 22 mg/l (Exposure time: 1 h)
ATE US (oral) 820.000 mg/kg body weight

ATE US (oral) 500.000 mg/kg body weight

Skin corrosion/irritation : Causes skin irritation.
  pH: 7 - 8.5

Serious eye damage/irritation : Causes serious eye irritation.
  pH: 7 - 8.5

Respiratory or skin sensitization : Not classified
Dexamethasone Sodium Phosphate Injection
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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.
- Specific target organ toxicity (single exposure): Not classified
- Specific target organ toxicity (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)

12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential

**Sodium sulfite (7757-83-7)**
- Log Pow: -4 (at 25 °C)

12.4. Mobility in soil
No additional information available

12.5. Other adverse effects
- Effect on the global warming: No known ecological damage caused by this product.

**SECTION 13: Disposal considerations**

13.1. Waste treatment methods
- Waste 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

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

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

SECTION 16: Other information

Full text of H-phrases:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral) Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation Category 1</td>
</tr>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Met. Corr. 1</td>
<td>Corrosive to metals Category 1</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>Reproductive toxicity Category 2</td>
</tr>
<tr>
<td>Skin Corr. 1A</td>
<td>Skin corrosion/irritation Category 1A</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation Category 2</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>Specific target organ toxicity (repeated exposure) Category 2</td>
</tr>
<tr>
<td>H290</td>
<td>May be corrosive to metals</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H361</td>
<td>Suspected of damaging fertility or the unborn child</td>
</tr>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

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.