Dexamethasone Sodium Phosphate Injection, USP

Section 1. Identification

GHS product identifier : Dexamethasone Sodium Phosphate Injection, USP
Synonyms : None.
Product code : NDC 0641-0367-21 NDC 0641-0367-25
Chemical family : Steroid.
Product type : Regulated prescription drug.
Container information : 1 mL vial.

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

Supplier's details : WEST-WARD PHARMACEUTICALS
EATONTOWN, NJ 07724

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3877

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture : CARCINOGENICITY - Category 2
TOXIC TO REPRODUCTION [Fertility] - Category 2
TOXIC TO REPRODUCTION [Unborn child] - Category 2

GHS label elements
Hazard pictograms : 

Signal word : Warning
Hazard statements : Suspected of damaging fertility or the unborn child.
Suspected of causing cancer.

Precautionary statements
Prevention : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
Response : IF exposed or concerned: Get medical attention.
Storage : Store locked up.
Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.
Hazards not otherwise classified : None known.
Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Other means of identification : None.

CAS number/other identifiers

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>%</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>0.1 - 1</td>
<td>100-51-6</td>
</tr>
<tr>
<td>1,2,3-Propanetricarboxylic acid, 2-hydroxy-, trisodium salt</td>
<td>1 - 5</td>
<td>68-04-2</td>
</tr>
<tr>
<td>Water</td>
<td>60 - 100</td>
<td>7732-18-5</td>
</tr>
<tr>
<td>Sodium sulphite</td>
<td>0.1 - 1</td>
<td>7757-83-7</td>
</tr>
<tr>
<td>Dexamethasone 21-(Disodium Phosphate)</td>
<td>0.1 - 1</td>
<td>2392-39-4</td>
</tr>
</tbody>
</table>

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin contact : Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No known significant effects or critical hazards.
Section 4. First aid measures

Protection of first-aiders:
No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

Notes to physician:
Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments:
No specific treatment.

Protection of first-aiders:
No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media:
Suitable extinguishing media:
Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media:
None known.

Specific hazards arising from the chemical:
No specific fire or explosion hazard.

Hazardous thermal decomposition products:
Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
phosphorus oxides
halogenated compounds
metal oxide/oxides

Special protective actions for fire-fighters:
No special protection is required.

Special protective equipment for fire-fighters:
Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures: Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities: Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.
Section 8. Exposure controls/personal protection

Control parameters

**Occupational exposure limits**

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>AIHA WEEL (United States, 10/2011). TWA: 10 ppm 8 hours.</td>
</tr>
</tbody>
</table>

**Appropriate engineering controls**

If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

**Environmental exposure controls**

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

**Hygiene measures**

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection**

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

**Skin protection**

**Hand protection**

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

**Body protection**

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Other skin protection**

Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Respiratory protection**

Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

**Appearance**

**Physical state**

Liquid. [Aqueous solution.]

**Color**

Colorless.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

7 to 8.5

**Melting point**

Not available.

**Boiling point**

Not available.
Section 9. Physical and chemical properties

Flash point  :  Closed cup: >101°C (>213.8°F)
Burn time  :  Not applicable.
Burn rate  :  Not applicable.
Evaporation rate  :  Not available.
Flammability (solid, gas)  :  Not available.
Lower and upper explosive (flammable) limits  :  Not available.
Vapor pressure  :  Not available.
Vapor density  :  Not available.
Relative density  :  Not available.
Solubility  :  Easily soluble in the following materials: cold water and hot water.
Solubility in water  :  Not available.
Partition coefficient: n-octanol/water  :  Not available.
Auto-ignition temperature  :  Not available.
Decomposition temperature  :  Not available.
SADT  :  Not available.
Viscosity  :  Not available.

Section 10. Stability and reactivity

Reactivity  :  No specific test data related to reactivity available for this product or its ingredients.
Chemical stability  :  The product is stable.
Possibility of hazardous reactions  :  Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid  :  No specific data.
Incompatible materials  :  Reactive or incompatible with the following materials: oxidizing materials, reducing materials and acids.
Hazardous decomposition products  :  Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Dose</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>LD50 Dermal</td>
<td>Rabbit</td>
<td>2000 mg/kg</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>LD50 Oral</td>
<td>Rat</td>
<td>1230 mg/kg</td>
<td>-</td>
</tr>
</tbody>
</table>

Irritation/Corrosion
Section 11. Toxicological information

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Score</th>
<th>Exposure</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Skin - Moderate irritant</td>
<td>Rabbit</td>
<td>-</td>
<td>24 hours 100 mg</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Skin - Mild irritant</td>
<td>Man</td>
<td>-</td>
<td>48 hours 16 mg</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Skin - Moderate irritant</td>
<td>Pig</td>
<td>-</td>
<td>100%</td>
<td>-</td>
</tr>
</tbody>
</table>

Sensitization
There is no data available.

Mutagenicity
There is no data available.

Carcinogenicity
There is no data available.

Reproductive toxicity
There is no data available.

Teratogenicity
There is no data available.

Specific target organ toxicity (single exposure)
There is no data available.

Specific target organ toxicity (repeated exposure)
There is no data available.

Aspiration hazard
There is no data available.

Information on the likely routes of exposure
Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects
- **Eye contact**: No known significant effects or critical hazards.
- **Inhalation**: No known significant effects or critical hazards.
- **Skin contact**: No known significant effects or critical hazards.
- **Ingestion**: No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics
- **Eye contact**: No known significant effects or critical hazards.
- **Inhalation**: Adverse symptoms may include the following:
  - reduced fetal weight
  - increase in fetal deaths
  - skeletal malformations
- **Skin contact**: Adverse symptoms may include the following:
  - reduced fetal weight
  - increase in fetal deaths
  - skeletal malformations
- **Ingestion**: Adverse symptoms may include the following:
  - reduced fetal weight
  - increase in fetal deaths
  - skeletal malformations

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure
Section 11. Toxicological information

Potential immediate effects: No known significant effects or critical hazards.
Potential delayed effects: No known significant effects or critical hazards.
Long term exposure
Potential immediate effects: No known significant effects or critical hazards.
Potential delayed effects: No known significant effects or critical hazards.
Potential chronic health effects
General: No known significant effects or critical hazards.
Carcinogenicity: Suspected of causing cancer. Risk of cancer depends on duration and level of exposure.
Mutagenicity: No known significant effects or critical hazards.
Teratogenicity: Suspected of damaging the unborn child.
Developmental effects: No known significant effects or critical hazards.
Fertility effects: Suspected of damaging fertility.

Numerical measures of toxicity
Acute toxicity estimates

<table>
<thead>
<tr>
<th>Route</th>
<th>ATE value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>35549.1 mg/kg</td>
</tr>
<tr>
<td>Inhalation (vapors)</td>
<td>1100 mg/L</td>
</tr>
</tbody>
</table>

Section 12. Ecological information

Toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Acute EC50 640 mg/L</td>
<td>Algae - Scenedesmus subspicatus</td>
<td>96 hours</td>
</tr>
<tr>
<td></td>
<td>Acute IC50 700 mg/L</td>
<td>Algae</td>
<td>72 hours</td>
</tr>
<tr>
<td></td>
<td>Acute LC50 10000 µg/l Fresh water</td>
<td>Fish - Lepomis macrochirus</td>
<td>96 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Test</th>
<th>Result</th>
<th>Dose</th>
<th>Inoculum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>OECD 301C 301C Ready Biodegradability - Modified MITI Test (I)</td>
<td>92 to 96 % - 28 days</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Bioaccumulative potential

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>LogP&lt;sub&gt;ow&lt;/sub&gt;</th>
<th>BCF</th>
<th>Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>1.1</td>
<td>-</td>
<td>low</td>
</tr>
</tbody>
</table>

Mobility in soil
Section 12. Ecological information

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

<table>
<thead>
<tr>
<th></th>
<th>DOT Classification</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Packing group</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Environmental hazards</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
</tr>
<tr>
<td>Additional information</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

AERG : Not applicable.

Special precautions for user : 

Transport within user’s premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.
Section 15. Regulatory information

U.S. Federal regulations

- **Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)**: Not listed
- **Clean Air Act Section 602 Class I Substances**: Not listed
- **Clean Air Act Section 602 Class II Substances**: Not listed
- **DEA List I Chemicals (Precursor Chemicals)**: Not listed
- **DEA List II Chemicals (Essential Chemicals)**: Not listed

**TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

**United States inventory (TSCA 8b)**: All components are listed or exempted.

**Massachusetts**:

None of the components are listed.

**New York**:

None of the components are listed.

**New Jersey**:

None of the components are listed.

**Pennsylvania**:

The following components are listed: Benzyl alcohol

**California Prop. 65**

No products were found.

**SARA 302/304**

**Composition/information on ingredients**

No products were found.

**SARA 304 RQ**: Not applicable.

**SARA 311/312**

**Classification**: Delayed (chronic) health hazard

**Composition/information on ingredients**

<table>
<thead>
<tr>
<th>Name</th>
<th>%</th>
<th>Fire hazard</th>
<th>Sudden release of pressure</th>
<th>Reactive</th>
<th>Immediate (acute) health hazard</th>
<th>Delayed (chronic) health hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>0.1 - 1</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
<td>Yes.</td>
<td>No.</td>
</tr>
<tr>
<td>Dexamethasone 21-(Disodium Phosphate)</td>
<td>0.1 - 1</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
<td>Yes.</td>
<td>Yes.</td>
</tr>
</tbody>
</table>

**State regulations**

**Massachusetts**

The following components are listed: Benzyl alcohol

**New York**

None of the components are listed.

**New Jersey**

None of the components are listed.

**Pennsylvania**

The following components are listed: Benzyl alcohol

**California Prop. 65**

No products were found.

**International regulations**

**International lists**

- **Australia inventory (AICS)**: All components are listed or exempted.
- **China inventory (IECSC)**: Not determined.
- **Japan inventory**: All components are listed or exempted.
- **Korea inventory**: All components are listed or exempted.
- **Malaysia Inventory (EHS Register)**: Not determined.
- **New Zealand Inventory of Chemicals (NZIoC)**: All components are listed or exempted.
- **Philippines inventory (PICCS)**: All components are listed or exempted.
- **Taiwan inventory (CSNN)**: Not determined.

**Chemical Weapons Convention List Schedule I Chemicals**: Not listed
Section 15. Regulatory information

Chemical Weapons Convention List Schedule II Chemicals: Not listed

Chemical Weapons Convention List Schedule III Chemicals: Not listed

Section 16. Other information

History

Date of issue mm/dd/yyyy: 06/15/2013
Version: 1
Revised Section(s): Not applicable.
Prepared by: KMK Regulatory Services Inc.

Key to abbreviations:
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
UN = United Nations

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