Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 08/14/2015 Date of issue: 08/14/2015 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP

Product Code: 0517-0720-01

Synonyms: Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP Betamethasone 21-disodium phosphate: 9(Alpha)-fluoro-l1(Beta), 17(Alpha), 21-trihydroxy-16(Beta)-methylpregna-l ,4-diene-3,20-dione 21-disodium phosphate; Betamethasone Acetate: 9(Alpha)-fluoro-16(Beta)-methyl-11(Beta), 17(Alpha), 21-trihydroxy-1,4-pregn

1.2. Intended Use of the Product

Use of the substance/mixture: This product contains both Betamethasone (as Betamethasone sodium phosphate) and Betamethasone Acetate, which are both fluorinated glucocorticoids used as anti-inflammatory or immunosuppressant agents. The product is used to treat inflammatory conditions of joints, and is typically administered via intramuscular injection.

1.3. Name, Address, and Telephone of the Responsible Party

Company
PharmaForce, Inc.
6610 New Albany Road East
New Albany, OH 43054
T 614-436-2222
www.pharmaforceinc.com

Distributor
American Regent, Inc.
One Luitpold Drive
P.O. Box 9001
Shirley, NY 11967
1-800-645-1706
www.luitpold.com

1.4. Emergency Telephone Number

Emergency Number: CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Skin Sens. 1 H317
Carc. 2 H351
Repr. 1B H360

Full text of H-phrases: see section 16

2.2. Elements

GHS-US Labeling

Hazard Pictograms (GHS-US): ! ☿

Signal Word (GHS-US): Danger

H351 - Suspected of causing 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.
P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
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2.3. Other Hazards
Exposure to this product may result in adverse effects. Exposure may cause suppression of suprarenal gland secretion, Cushing syndrome, water retention, electrolyte imbalance, and hyperglycemia. Refer to patient insert for more information.

2.4. Unknown Acute Toxicity (GHS-US)
No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance
Not applicable

3.2. Mixture

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<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
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<td>98.32</td>
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</tr>
<tr>
<td>Sodium phosphate dibasic</td>
<td>(CAS No) 7558-79-4</td>
<td>0.71</td>
<td>Not classified</td>
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<td>Phosphoric acid, monosodium salt, monohydrate</td>
<td>(CAS No) 10049-21-5</td>
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<td>Acute Tox. 4 (Oral), H302; Acute Tox. 2 (Inhalation: dust,</td>
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<td>mist), H332; Skin Irrit. 2, H315; Skin Irrit. 2A, H319; STOT</td>
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<td>Eye Irrit. 2A, H319; STOT SE 3, H335; Aquatic Chronic 3, H412;</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Flush with copious quantities of water for 15 minutes. Seek medical attention.

First-aid Measures After Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting.
4.2. Most important symptoms and effects, both acute and delayed
Symptoms/Injuries: May cause an allergic skin reaction. There are potential chronic health effects to consider. When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract. Refer to patient insert for more information.

Symptoms/Injuries After Inhalation: May cause respiratory irritation.
Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. May cause skin irritation.
Symptoms/Injuries After Eye Contact: May cause eye irritation.

Chronic Symptoms: Suspected of causing cancer. May damage fertility or the unborn child. Prolonged exposure may cause suppression of suprarenal gland secretion, Cushing syndrome, water retention, electrolyte imbalance, and hyperglycemia. Repeated exposure may harm endocrine system.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed
If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media
Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture
Fire Hazard: Not flammable.
Explosion Hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters
Firefighting Instructions: Exercise caution when fighting any chemical fire. Do not breathe fumes from fires or vapors from decomposition. Use water spray or fog for cooling exposed containers.

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: Avoid all unnecessary exposure. Do not breathe vapour or mist.

6.1.1. For Non-emergency Personnel
Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8.2.


6.1.2. For Emergency Responders
Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions
Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up
For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

6.4. Reference to Other Sections
See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling
Additional Hazards When Processed: Use only as directed by the information identified in the package insert.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work. Avoid breathing vapors, mist, spray. Avoid contact with skin, eyes, and clothing.

7.2. Conditions for Safe Storage, Including Any Incompatibilities
Technical Measures: Comply with applicable regulations.
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Storage Conditions: Store in original container. Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.


Storage Temperature: 20 - 25 °C (68 - 77 °F)

7.3. Specific End Use(s)

This product contains both Betamethasone (as Betamethasone sodium phosphate) and Betamethasone Acetate, which are both fluorinated glucocorticoids used as anti-inflammatory or immunosuppressant agents. The product is used to treat inflammatory conditions of joints, and is typically administered via intramuscular injection.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.


Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection: In case of inadequate ventilation wear respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State: Liquid

Appearance: White suspended powder in clear, colorless liquid

Odor: Odorless

Odor Threshold: No data available

pH: 6.8 - 7.2

Evaporation Rate: No data available

Melting Point: No data available

Freezing Point: No data available

Boiling Point: = 100 °C (212 °F)

Flash Point: Not applicable

Auto-ignition Temperature: No data available

Decomposition Temperature: No data available

Flammability (solid, gas): No data available

Vapor Pressure: No data available

Relative Vapor Density at 20 °C: No data available

Specific Gravity: Approximate to Water.

Solubility: Acetate derivative is insoluble, phosphate derivative is soluble in water.

Partition Coefficient: N-Octanol/Water: No data available

Viscosity: No data available
9.2. Other Information  No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:  Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability:  Stable under recommended handling and storage conditions (see Section 7).
10.3. Possibility of Hazardous Reactions:  Hazardous polymerization will not occur.
10.4. Conditions to Avoid:  Direct sunlight, extremely high or low temperatures, and incompatible materials.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity:  Not classified


LD₅₀ Oral Rat:  1877 mg/kg

Sodium phosphate dibasic (7558-79-4)

LD₅₀ Oral Rat:  > 2000 mg/kg
LD₅₀ Dermal Rat:  > 2000 mg/kg

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)

ATE (Oral):  500.00 mg/kg body weight
ATE (Dermal):  1,100.00 mg/kg body weight
ATE (Dust/Mist):  1.50 mg/l/4h

Quaternary ammonium compounds, alkylbenzyldimethyl, chlorides (8001-54-5)

LD₅₀ Oral Rat:  304.5 mg/kg
LD₅₀ Dermal Rat:  1420 mg/kg

Skin Corrosion/Irritation:  Not classified
pH:  6.8 - 7.2

Serious Eye Damage/Irritation:  Not classified
pH:  6.8 - 7.2

Respiratory or Skin Sensitization:  Not classified
Germ Cell Mutagenicity:  Not classified
Carcinogenicity:  Suspected of causing cancer.
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

Symptoms/Injuries After Inhalation:  May cause respiratory irritation.
Symptoms/Injuries After Skin Contact:  May cause an allergic skin reaction. May cause skin irritation.
Symptoms/Injuries After Eye Contact:  May cause eye irritation.
Symptoms/Injuries After Ingestion:  Potent pharmaceutical ingestion may be harmful or have adverse effects.

Chronic Symptoms:  Suspected of causing cancer. May damage fertility or the unborn child. Prolonged exposure may cause suppression of suprarenal gland secretion, Cushing syndrome, water retention, electrolyte imbalance, and hyperglycemia. Repeated exposure may harm endocrine system.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Quaternary ammonium compounds, alkylbenzyldimethyl, chlorides (8001-54-5)

LC₅₀ Fish 1:  0.223 - 0.46 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC₅₀ Daphnia 1:  0.018 mg/l
LC 50 Fish 2:  0.823 - 1.61 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

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12.2. Persistence and Degradability

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| Persistence and Degradability | Not established. |

12.3. Bioaccumulative Potential

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP

| Bioaccumulative Potential | Not established. |

12.4. Mobility in Soil

| Mobility in Soil | No additional information available |

12.5. Other Adverse Effects

| Other Information | Avoid release to the environment |

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT

| Not regulated for transport |

14.2. In Accordance with IMDG

| Not regulated for transport |

14.3. In Accordance with IATA

| Not regulated for transport |

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

| Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP |

| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard |
| Delayed (chronic) health hazard |

| Sodium phosphate dibasic (7558-79-4) |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

| Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-], disodium salt, dihydrate (6381-92-6) |
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard |

| Water (7732-18-5) |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

15.2 US State Regulations

| Sodium phosphate dibasic (7558-79-4) |
| U.S. - Massachusetts - Right To Know List |
| U.S. - New Jersey - Right to Know Hazardous Substance List |
| U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List |
| U.S. - Pennsylvania - RTK (Right to Know) List |

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

| Revision Date | 08/14/2015 |
| Other Information | This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200. |

GHS Full Text Phrases:

- Acute Tox. 2 (Inhalation:dust,mist) Acute toxicity (inhalation:dust,mist) Category 2
- Acute Tox. 3 (Inhalation) Acute toxicity (inhalation) Category 3
- Acute Tox. 4 (Dermal) Acute toxicity (dermal) Category 4
- Acute Tox. 4 (Inhalation:dust,mist) Acute toxicity (inhalation:dust,mist) Category 4
- Acute Tox. 4 (Oral) Acute toxicity (oral) Category 4
- Aquatic Acute 1 Hazardous to the aquatic environment - Acute Hazard Category 1
- Aquatic Chronic 1 Hazardous to the aquatic environment - Chronic Hazard Category 1
- Aquatic Chronic 3 Hazardous to the aquatic environment - Chronic Hazard Category 3
- Carc. 2 Carcinogenicity Category 2
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<th>Code</th>
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<td>Eye Dam. 1</td>
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<td>Harmful if swallowed</td>
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<td>H312</td>
<td>Harmful in contact with skin</td>
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<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
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<td>H315</td>
<td>Causes skin irritation</td>
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<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
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<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
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<td>H319</td>
<td>Causes serious eye irritation</td>
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<td>H335</td>
<td>May cause respiratory irritation</td>
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<td>H351</td>
<td>Suspected of causing cancer</td>
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<tr>
<td>H360</td>
<td>May damage fertility or the unborn child</td>
</tr>
<tr>
<td>H361</td>
<td>Suspected of damaging fertility or the unborn child</td>
</tr>
<tr>
<td>H372</td>
<td>Causes damage to organs through prolonged or repeated exposure</td>
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<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
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<tr>
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<td>Very toxic to aquatic life</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects</td>
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Refer to Luitpold/American Regent prescribing information for further information at: http://americanregent.com/AllProducts.aspx

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SDS US (GHS HazCom)