

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

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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-11(Beta), 17(Alpha), 21-trihydroxy-16(Beta)-methylpregna-1,4-diene-3,20-dione 21-disodium phosphate; Betamethasone Acetate: 9(Alpha)-fluoro-16(Beta)-methyl-11(Beta), 17(Alpha), 21-trihydroxy-1,4-pregn Betamethasone 21-disodium phosphate: 9(Alpha)-fluoro-11(Beta), 17(Alpha), 21-trihydroxy-16(Beta)-methylpregna-1,4-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. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H317 - May cause an allergic skin reaction.

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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P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

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

Name	Product Identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	98.32	Not classified
Sodium phosphate dibasic	(CAS No) 7558-79-4	0.71	Not classified
Phosphoric acid, monosodium salt, monohydrate	(CAS No) 10049-21-5	0.34	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonooxy)-, disodium salt, (11.beta.,16.beta.)-	(CAS No) 151-73-5	0.3	Acute Tox. 4 (Oral), H302 Acute Tox. 2 (Inhalation:dust,mist), H330 Eye Irrit. 2B, H320 Repr. 2, H361 STOT RE 1, H372
9-Fluoro-11.beta.,17,21-trihydroxy-16.beta.-methylpregna-1,4-diene-3,20-dione 21-acetate	(CAS No) 987-24-6	0.3	Acute Tox. 3 (Inhalation), H331 Skin Sens. 1, H317 Carc. 2, H351 Repr. 1B, H360 STOT RE 2, H373
Quaternary ammonium compounds, alkylbenzyl dimethyl, chlorides	(CAS No) 8001-54-5	0.02	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, disodium salt, dihydrate	(CAS No) 6381-92-6	0.01	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 Aquatic Chronic 3, H412

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.

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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.

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.

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.

Emergency Procedures: Evacuate unnecessary personnel.

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.

Incompatible Products: Strong bases. Strong oxidizers. Strong acids.

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.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



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

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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.
- 10.5. **Incompatible Materials:** Strong oxidizers. Strong bases. Strong acids.
- 10.6. **Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO₂). Sodium oxides. Halogenated compounds. Nitrogen oxides. Phosphorous oxides. Hydrogen fluoride.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy)-, disodium salt, (11.beta.,16.beta.)- (151-73-5)	
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, alkylbenzyltrimethyl, 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, alkylbenzyltrimethyl, 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

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Bioaccumulative Potential	Not established.

12.4. 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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Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Eye Irrit. 2B	Serious eye damage/eye irritation Category 2B
Repr. 1B	Reproductive toxicity Category 1B
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H320	Causes eye irritation
H330	Fatal if inhaled
H331	Toxic if inhaled
H332	Harmful if inhaled
H335	May cause respiratory irritation
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child
H361	Suspected of damaging fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

Refer to Luitpold/American Regent prescribing information for further information at: <http://americanregent.com/AllProducts.aspx>

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.

SDS US (GHS HazCom)