SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME
BETAMETHASONE SODIUM PHOSPHATE, USP

PRODUCT CODE
0195

SUPPLIER
MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063

MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2

MEDISCA Australia PTY LTD
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
Unit 7, Heritage Business Park
5-9 Ricketty Street, Mascot, NSW 2020

EMERGENCY PHONE
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126

USES
Corticosteroid (glucocorticoid); Anti-Inflammatory Agent

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Acute Toxicity - Oral (Category 4)
Toxic to Reproduction (Category 2)
Chronic Aquatic Toxicity (Category 2)
Eye Irritation (Category 2B)
Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (endocrine system)

PICTOGRAM

SIGNAL WORD
Danger

HAZARD STATEMENT(S)
Harmful if swallowed
Suspected of damaging fertility or the unborn child
Causes damage to organs through prolonged or repeated
Causes eye irritation
Toxic to aquatic life with long lasting effects.
May cause allergic reaction
May be fatal if inhaled

AUSTRALIA-ONLY HAZARDS
Not Applicable.

PRECAUTIONARY STATEMENT(S)
Prevention
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves, protective clothing, eye protection, face protection.
Do not breathe dust/fume/gas/mist/vapors/spray.
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Avoid release to the environment
SAFETY DATA SHEET

Response

IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
IF EXPOSED OR CONCERNED: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
COLLECT SPILLAGE

Storage

Disposal

HMIS CLASSIFICATION

Health Hazard 2
Flammability 0
Reactivity 0
Personal Protection G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME

Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy)-, disodium salt, (11β,16β)

BOTANICAL NAME

Not applicable

SYNONYM

Betamethasone 21-phosphate disodium salt; Betamethazone disodium phosphate

CHEMICAL FORMULA

C22H28FNa2O8PC

CAS NUMBER

151-73-5

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

516.4072

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>BETAMETHASONE SODIUM PHOSPHATE</td>
<td>151-73-5</td>
<td>100</td>
</tr>
</tbody>
</table>

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

NOTES

Chemical family: Corticosteroid.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

SYMPTOMS AND EFFECTS

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.
SAFETY DATA SHEET

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT
On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in tight containers, protected from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: BETAMETHASONE SODIUM PHOSPHATE    CAS #: 151-73-5

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.
SAFETY DATA SHEET

SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

NOTES
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICAL STATE</td>
<td>Solid</td>
</tr>
<tr>
<td>DESCRIPTION</td>
<td>White to practically white, odorless powder. Is hygroscopic.</td>
</tr>
<tr>
<td>SOLUBILITY</td>
<td>Freely soluble in water and in methanol; practically insoluble in acetone and in chloroform.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Odorless</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td>ODOR THRESHOLD</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>7.5 - 9 (1%)</td>
</tr>
<tr>
<td>MELTING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>BOILING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>FREEZING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>FLASH POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY</td>
<td>Not available</td>
</tr>
<tr>
<td>EVAPORATION RATE</td>
<td>Not available</td>
</tr>
<tr>
<td>EXPLOSIVE LIMIT</td>
<td>Not available</td>
</tr>
<tr>
<td>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>VAPOR PRESSURE</td>
<td>&lt; 0.0000001 kPa (25°C)</td>
</tr>
<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>RELATIVE DENSITY (WATER = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>4.07 (20°C)</td>
</tr>
<tr>
<td>AUTO-IGNITION TEMPERATURE</td>
<td>Not available</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE</td>
<td>Not available</td>
</tr>
<tr>
<td>VISCOSITY</td>
<td>Not available</td>
</tr>
</tbody>
</table>

NOTES
The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACTIVITY</td>
<td>Not established.</td>
</tr>
<tr>
<td>STABILITY</td>
<td>Stable under recommended storage conditions.</td>
</tr>
<tr>
<td>HAZARDOUS DECOMPOSITION PRODUCTS</td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.</td>
</tr>
<tr>
<td>HAZARDOUS POLYMERIZATION</td>
<td>Will not occur.</td>
</tr>
<tr>
<td>POSSIBILITY OF HAZARDOUS REACTION</td>
<td>Not established.</td>
</tr>
<tr>
<td>CONDITIONS TO AVOID</td>
<td>Moisture, sunlight and extreme temperatures.</td>
</tr>
</tbody>
</table>

SECTION 11: TOXICOLOGICAL INFORMATION
SAFETY DATA SHEET

ACUTE TOXICITY

Oral: Rat: LD50: (mg/kg): 1877
Dermal: Rabbit LD50: (mg/kg): Not available
Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

Based on available data, the classification criteria are not met.
Skin irritancy, Result: Non-irritating. Species: Rabbit.

SERIOUS EYE DAMAGE/EYE IRRITATION

Eye irritancy, Result: Mild, reversible ocular irritation; reversible at 7 days. Species: Rabbit.

REPRODUCTIVE TOXICITY

Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in the incidence of cleft palate was seen in some human studies. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.
Species: Rabbit: 0.05 mg/kg Developmental study (Betamethasone dipropionate)
Result: Birth defects included umbilical hernia, cephalocele, and cleft palate.
Species: Rabbit: 1 mg/kg Reproductive study (Betamethasone dipropionate)
Result: Dose-related increases in fetal resorption.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Causes damage to organs (endocrine system, immune system suppression) through prolonged or repeated exposure.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Based on available data, the classification criteria are not met.

ASPIRATION HAZARDS

Symptoms related to the physical, chemical, and toxicological characteristics:
Delayed and immediate effects of exposure:

MEDICATIONS AFFECTED BY EXPOSURE:

Cross sensitivity:
Persons sensitive to one corticosteroid may be sensitive to this material also.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

SAFETY DATA SHEET

POTENTIAL HEALTH EFFECTS

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May be fatal if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.</td>
</tr>
<tr>
<td>Eyes</td>
<td>Causes eye irritation.</td>
</tr>
</tbody>
</table>

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

- EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 1.9
- LC50: 96 Hr: Fish: (mg/L): Not available
- EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

- Biodegradation: 28 % (Minimally biodegradable).
- Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable

BIOACCUMULATIVE POTENTIAL

- LogPow: 4.07 (20°C)

MOBILITY IN SOIL

- Freely soluble in water.

OTHER ADVERSE EFFECTS

- This product is not intended to be released into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL

- Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA

<table>
<thead>
<tr>
<th>UN PROPER SHIPPING NAME</th>
<th>Not dangerous good</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN NUMBER</td>
<td>Not applicable</td>
</tr>
<tr>
<td>CLASS</td>
<td>Not applicable</td>
</tr>
<tr>
<td>PACKING GROUP</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

AUSTRALIA

<table>
<thead>
<tr>
<th>UN PROPER SHIPPING NAME</th>
<th>Not dangerous good</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN NUMBER</td>
<td>Not applicable</td>
</tr>
<tr>
<td>CLASS</td>
<td>Not applicable</td>
</tr>
<tr>
<td>PACKING GROUP</td>
<td>Not applicable</td>
</tr>
<tr>
<td>HAZCHEM</td>
<td>Not applicable</td>
</tr>
<tr>
<td>ENVIRONMENTAL HAZARDS</td>
<td>Not available</td>
</tr>
<tr>
<td>SPECIAL SHIPPING INFORMATION</td>
<td>Not applicable</td>
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</table>
SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.85</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>BETAMETHASONE SODIUM PHOSPHATE 151-73-5</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
</tr>
</thead>
<tbody>
<tr>
<td>BETAMETHASONE SODIUM PHOSPHATE 151-73-5</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
<td>N/L</td>
</tr>
</tbody>
</table>

*Listed as Betamethasone

NOTES

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
CAS = Chemical Abstract Service; GHS = Global Harmonized System; OSHA PEL = Occupational Safety & Health Administration Permissible Exposure Limits; TWA = Time Weighted Average; HSIS = Hazardous Substances Information System; STEL = Short Term Exposure Limit; AIHA WEEL = American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 = Lethal Dose, 50%; IARC = International Agency for Research on Cancer; NTP = National Toxicology Program; WHMIS = Workplace Hazardous Materials Information System; SARA = Superfund Amendments and Reauthorization Act; EPA = Environmental Protection Agency; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; HMIS = Hazardous Materials Information System; NIOSH = National Institute for Occupational Safety and Health; MSHA = Mine Safety and Health Administration; ACGIH = American Conference of Governmental Industrial Hygienists; IDHL = Immediately Dangerous to Health or Life; TLV = Threshold Limit Value; HSE = Health and Safety Executive; REL = Recommended Exposure Limit

LAST REVISION
11/2018

SUPERSEDES
11/2018

DISCLAIMER
This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.