SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: BETAMETHASONE VALERATE, USP (Micronized)
PRODUCT CODE: 0004
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:
Glucocorticoid

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION:
Acute Toxicity - Oral (Category 5)
Toxic to Reproduction (Category 1B)
Chronic Aquatic Toxicity (Category 2)
Skin Irritation (Category 2)
Specific Target Organ Toxicity - Repeated Exposure (Category 2) - endocrine system

PICTOGRAM:

SIGNAL WORD:
Warning

HAZARD STATEMENT(S):
May cause damage to organs through prolonged or repeated exposure.
May damage fertility or the unborn child
Toxic to aquatic life with long lasting effects
Causes skin irritation.
May cause allergic reaction
May be harmful if swallowed

AUSTRALIA-ONLY HAZARDS:
Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S):
Prevention:
Wash thoroughly after handling
Do not breathe dust/fume/gas/mist/ vapors/spray.
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.
Avoid release to the environment.

Response:
IF EXPOSED OR CONCERNED: Get medical advice/attention.
COLLECT SPILLAGE
IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

Storage:
Store locked up.
SAFETY DATA SHEET

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>9-Fluoro-11ß,21-trihydroxy-16ß-methylpregna-1, 4- diene-3,20-dione 17-valerate</th>
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<tbody>
<tr>
<td>BOTANICAL NAME</td>
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</tr>
<tr>
<td>SYNONYM</td>
<td>Betamethasone 17-valerate</td>
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<tr>
<td>CHEMICAL FORMULA</td>
<td>C_{27}H_{37}FO_{6}</td>
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<tr>
<td>CAS NUMBER</td>
<td>2152-44-5</td>
</tr>
<tr>
<td>ALTERNATE CAS NUMBER</td>
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<tr>
<td>MOLECULAR WEIGHT</td>
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<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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<tbody>
<tr>
<td>BETAMETHASONE VALERATE</td>
<td>2152-44-5</td>
<td>100</td>
</tr>
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</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.

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

**SYMPTOMS AND EFFECTS**

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.

**EXTINGUISHING MEDIA**
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS**
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES
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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.

STORAGE CONDITIONS
Store in original container, tightly sealed container, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight, light-resistant containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: BETAMETHASONE VALERATE  CAS #: 2152-44-5

| Chemical Name: BETAMETHASONE VALERATE  CAS #: 2152-44-5
<table>
<thead>
<tr>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
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<tr>
<td>ACGIH TLV</td>
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<td>N/L</td>
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<td>NIOSH</td>
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<td>AIHA WEEL</td>
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<td>Safe Work Australia HSIS</td>
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<tr>
<td>HSE</td>
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<td>N/L</td>
<td>N/L</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.

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

NOTE
USP: ELV: Industrial use: TWA: 10 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Solid

DESCRIPTION
White to practically white, odorless powder.
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SOLUBILITY  Practically insoluble in water; freely soluble in acetone and in chloroform; soluble in alcohol; slightly soluble in benzene and in ether.

ODOR  Odorless

FLAMMABILITY  May be combustible at high temperature

ODOR THRESHOLD  Not available

BOILING POINT  Not available

FREEZING POINT  (190 - 192)°C, (374-377.6)°F

SPECIFIC GRAVITY  Not available

EVAPORATION RATE  Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)  Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)  Not available

VAPOR DENSITY (AIR = 1)  Not available

RELATIVE DENSITY (WATER = 1)  Not available

AUTO-IGNITION TEMPERATURE  Not available

DECOMPOSITION TEMPERATURE  Not available

MELTING POINT  (190 - 192)°C, (374-377.6)°F

FLASH POINT  Not available

EXPLOSIVE LIMIT  Not available

VAPOR PRESSURE  < 0.0000001 kPa

(log P (OCTANOL-WATER)  3.909 (20°C)

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY  Not established

STABILITY  Stable under recommended storage conditions


HAZARDOUS DECOMPOSITION PRODUCTS  Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

HAZARDOUS POLYMERIZATION  Will not occur

POSSIBILITY OF HAZARDOUS REACTION  Not established

CONDITIONS TO AVOID  Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY  Oral: Rat: LD50: (mg/kg): >3000
Dermal: Rabbit LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION  Causes skin irritation.
Local effects
0.1 % Irritancy test; Result: Irritant; Species: Rabbit; Organ: Skin; Severity: Mild.
0.1 % Irritancy test; Result: Non-irritant; Species: Rabbit; Organ: Skin
1 % Irritancy test; Result: Irritant; Species: Human; Organ: Skin; Severity: Mild.
1 % Irritancy test; Result: Irritant; Species: Human; Organ: Skin; Severity: Moderate.
Based on available data, the classification criteria are not met.

**Local effects**
- 0.1 % Irritancy test; Result: Non-irritant; Species: Rabbit; Organ: Eye

**Respiratory sensitization**
Due to lack of data the classification is not possible.

**Skin sensitization**
Based on available data, the classification criteria are not met.
Rare occurrences of dermal hypersensitivity reactions with therapeutic use of this material have been reported.

**Carcinogenicity**
- OSHA: BETAMETHASONE VALERATE is not listed.
- NTP: BETAMETHASONE VALERATE is not listed.
- IARC: BETAMETHASONE VALERATE is not evaluated.
- California: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**Reproductive toxicity**
- Suspected of damaging the unborn child. May cause congenital malformation.
- May damage fertility or the unborn child.
- Animal studies with some corticosteroids have shown cleft palate and inhibited fetal growth. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. Small increase in 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. A related material has caused birth defects in animals. Adverse fetal effects were seen in animal studies with a related material.

**Specific target organ toxicity - single exposure**
Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure**
Causes damage to organs (endocrine system) through prolonged or repeated exposure.

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

**Signs and symptoms of exposure**
Symptoms related to the physical, chemical, and toxicological characteristics
- Corticosteroids: Nausea, Vomiting, Headache, Acne, Increased hair growth, Light-headedness, Weakness, Increased sweating, Eye pain, Vision changes, Mental or behavioral changes, Swelling, Numbness, Infection, Delayed wound healing, Thinning skin, Bruising, Purple lines on skin, Bone fractures, Back pain, Joint pain or stiffness, Increased appetite, Redistribution of body fat, Menstrual irregularities, Impotence, Tremors.
- Delayed and immediate effects of exposure
- Corticosteroids: Fluid and electrolyte imbalance, Cushing's syndrome, Adrenal suppression, Immune system depression, Withdrawal.
- Cross sensitivity Persons sensitive to one corticosteroid may be sensitive to this material also.
- Medical conditions aggravated by exposure
- Corticosteroids: Heart disease, High blood pressure, Diabetes, Epilepsy, Glaucoma, Hypothyroidism, Osteoporosis, Peptic ulcer, Systemic fungal infection, Mental disorders, Impaired liver or kidney function.

**Potential health effects**
- **Inhalation**
  - May be harmful if inhaled. May cause respiratory tract irritation.
- **Ingestion**
  - May be harmful if swallowed.
- **Skin**
  - May be harmful if absorbed through skin. Causes skin irritation.
- **Eyes**
  - May cause eye irritation.

**Notes**
Adverse reactions include peptic ulcer, pancreatitis, abdominal distention, ulcerative, esophagitis, convulsions, increased intracranial pressure, vertigo, headache, musculoskeletal effects including osteoporosis, fluid and electrolyte disturbances, ophthalmic effects such as cataracts, glaucoma and exophthalmos. Overexposure can cause suppression of adrenal gland secretion, Cushing’s syndrome, water retention, electrolyte imbalance, and hyperglycaemia.
SECTION 12: ECOLOGICAL INFORMATION

**TOXICITY**
- EC50: 48 Hr: Crustacea: (mg/L): 1.9
- LC50: 96 Hr: Fish: (mg/L): Not available
- IC50: 72 Hr: Algae: (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**
- Minimally biodegradable

**BIOACCUMULATIVE POTENTIAL**
- LogPow: 3.909 (20°C)

**MOBILITY IN SOIL**
- Practically insoluble in water

**OTHER ADVERSE EFFECTS**
- Not available
- 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**
- UN PROPER SHIPPING NAME: Not dangerous good
- UN NUMBER: Not applicable
- CLASS: Not applicable
- PACKING GROUP: Not applicable

**AUSTRALIA**
- UN PROPER SHIPPING NAME: Not dangerous good
- UN NUMBER: Not applicable
- CLASS: Not applicable
- PACKING GROUP: Not applicable
- HAZCHEM: Not applicable
- ENVIRONMENTAL HAZARDS: Not applicable
- SPECIAL SHIPPING INFORMATION: Not applicable

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 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>BETAMETHASONE VALERATE, 2152-44-5</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>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed
**SAFETY DATA SHEET**

**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>
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</thead>
<tbody>
<tr>
<td>BETAMETHASONE VALERATE, 2152-44-5</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
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</table>

**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**

09/2016

**SUPERSEDES**

05/2015

**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.