SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: FLUCINOLONE ACETONIDE, USP/EP (Anhydrous) (Micronized)

PRODUCT CODE: 0022

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 used topically for its glucocorticoid activity.

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION:
Acute Toxicity - Oral (Category 4)
Acute Toxicity - Dermal (Category 1)
Skin Irritation (Category 2)
Toxic to Reproduction (Category 2)
Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (endocrine system)

PICTOGRAM:

SIGNAL WORD:
Danger

HAZARD STATEMENT(S):
Harmful if swallowed.
Fatal in contact with skin.
Suspected of damaging fertility or the unborn child.
Causes damage to organs through prolonged or repeated exposure.
Causes skin irritation.
Causes serious eye irritation.

AUSTRALIA-ONLY HAZARDS:
Not Applicable.

PRECAUTIONARY STATEMENT(S):
Prevention
Wash thoroughly after handling.
Do not get in eyes, on skin, or on clothing.
Do not eat, drink or smoke when using this product.
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.

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Response
IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth.
IF ON SKIN (HAIR): Wash with plenty of water; Immediately call a poison center or medical professional. Take off immediately all contaminated clothing and wash it before reuse.
IF EXPOSED OR CONCERNED: Get medical advice/attention.
Get medical advice/attention if you feel unwell.

Storage
Store locked up.

Disposal
Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION
Health Hazard 2
Flammability 0
Reactivity 0
Personal Protection G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME 6a-9-Difluoro-11ß,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione, cyclic 16,17-acetal with acetone, Anhydrous

BOTANICAL NAME Not applicable

SYNONYM 6alpha-Fluorotriamcinolone acetonide, Fluocinolone 16,17-acetonide, Anhydrous

CHEMICAL FORMULA C24H30F2O6

CAS NUMBER 67-73-2

ALTERNATE CAS NUMBER Not applicable

MOLECULAR WEIGHT 452.491

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLUCINOLONE ACETONIDE</td>
<td>67-73-2</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.
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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

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

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: FLUCINOLONE ACETONIDE CAS #: 67-73-2

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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</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

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FLUCINOLONE ACETONIDE, USP/EP (Anhydrous) (Micronized)
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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. Fumehood, eye wash station, and safety shower.

NOTES

USP: ELV: TWA (Industrial Use): 0.04 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PHYSICAL STATE</th>
<th>Solid</th>
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<tbody>
<tr>
<td>DESCRIPTION</td>
<td>White or practically white, odorless, crystalline powder. Is stable in air.</td>
</tr>
<tr>
<td>SOLUBILITY</td>
<td>Insoluble in water; soluble in methanol, in acetone and in anhydrous ethanol; slightly soluble in ether 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>
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<tr>
<td>ODOR THRESHOLD</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Not available</td>
</tr>
<tr>
<td>MELTING POINT</td>
<td>(265 - 274)°C, (509-525.2)°F (decomposes)</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not available</td>
</tr>
<tr>
<td>FREEZING POINT</td>
<td>(265 - 274)°C, (509-525.2)°F</td>
</tr>
<tr>
<td>Flash Point</td>
<td>304 °C, 579.2 °F</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>
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</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>2.48 (20°C)</td>
</tr>
<tr>
<td>AUTO-IGNITION TEMPERATURE</td>
<td>Not available</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE</td>
<td>(265 - 274)°C, (509-525.2)°F</td>
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<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

**REACTIVITY**

Not established.

**STABILITY**

Stable under recommended storage conditions.

**MATERIALS TO AVOID**

Strong oxidants.

**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): 400 - 1200  
  Dermal: Rabbit: LD50: (mg/kg): 2.31  
  Inhalation: Rat: LC50: (mg/L/4hr): Not available

### SKIN CORROSION/IRRITATION

Causes skin irritation.  
Irritation test; Result: Moderate irritant.; Species: Human; Organ: Skin.

### SERIOUS EYE DAMAGE/EYE IRRITATION

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

### RESPIRATORY OR SKIN SENSITIZATION

Respiratory sensitization: Due to lack of data the classification is not possible.  
Skin sensitization: Based on available data, the classification criteria are not met.  
Suspected skin sensitizer: The Toolbox profiler Protein binding alerts for skin sensitization by OASIS v1.3 gives an alert for skin sensitisation.

### GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.  
Suspected mutagen: The Toolbox profiler Protein binding alerts for Chromosomal aberration by OASIS v1.1 gives an alert for mutagenicity.

#### Mutagenicity

- **Ames test**  
  Result: Negative.
- **In vivo mouse bone marrow micronucleus test**  
  Result: Negative.
- **Mouse lymphoma TK assay**  
  Result: Negative.
- **Syrian hamster embryo cell transformation assay, viral enhanced.**  
  Result: Positive.

### CARCINOGENICITY

- **OSHA**  
  FLUOCINOLONE ACETONIDE is not listed.
- **NTP**  
  FLUOCINOLONE ACETONIDE is not listed.
- **IARC**  
  FLUOCINOLONE ACETONIDE is not evaluated.
- **California Proposition 65**  
  This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

### ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.  
Suspected carcinogen: The Toolbox profiler Carcinogenicity (genotox and nongenotox) alerts by ISS gives an alert for carcinogenicity.

### REPRODUCTIVE TOXICITY

Suspected of damaging fertility or the unborn child.

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.

- **Reproductivity**  
  0.05 mg/kg/day Reproductivity and development study in rabbits and rats, administered subcutaneously during gestation.  
  Result: Maternal toxicity, fetal death and teratogenicity.  
  0.125 mg/kg Reproductivity and development study in rabbits, administered subcutaneously during gestation.  
  Result: Maternal toxicity and fetal death.

### SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

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

Delayed and immediate effects of exposure:

Cross sensitivity:
Persons sensitive to other corticosteroids may also be sensitive to this material.

Medical conditions aggravated by exposure:

SIGNS AND SYMPTOMS OF EXPOSURE

May be harmful if inhaled. May cause respiratory tract irritation.

POTENTIAL HEALTH EFFECTS

Inhalation
May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion
Harmful if swallowed.

Skin
Fatal in contact with skin. Causes skin irritation.

Eyes
Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Crustacea: (mg/L): Not available
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
Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL
Log Pow: 2.48 (20°C)

MOBILITY IN SOIL
Insoluble in water. (Water solubility: 11 mg/L) (25°C)
Henry's Law Constant: 1.96E-12 atm-m³/mole (25°C)

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

UN PROPER SHIPPING NAME
TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER
2811
CLASS
6.1
PACKING GROUP

AUSTRALIA

UN PROPER SHIPPING NAME

UN NUMBER

CLASS

PACKING GROUP

HAZCHEM

ENVIRONMENTAL HAZARDS

SPECIAL SHIPPING INFORMATION

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 Right-to-know</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLUOCINOLONE ACETONIDE 67-73-2</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>FLUOCINOLONE ACETONIDE 67-73-2</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
<td>N/L</td>
</tr>
</tbody>
</table>

SECTION 16: OTHER INFORMATION

REFERENCES

ABBREVIATIONS AND ACRONYMOS

NATIONAL 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

SUPERSEDES

02/2019

01/2016
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.