## SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th><strong>PRODUCT NAME</strong></th>
<th>FLUDROCORTISONE ACETATE, USP (Micronized)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRODUCT CODE</strong></td>
<td>0129</td>
</tr>
<tr>
<td><strong>SUPPLIER</strong></td>
<td>MEDISCA Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.932.1039</td>
</tr>
<tr>
<td></td>
<td>661 Route 3, Unit C, Plattsburgh, NY, 12901</td>
</tr>
<tr>
<td></td>
<td>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118</td>
</tr>
<tr>
<td></td>
<td>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Pharmaceutique Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.665.6334</td>
</tr>
<tr>
<td></td>
<td>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8</td>
</tr>
<tr>
<td></td>
<td>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Australia PTY LTD</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.300.786.392</td>
</tr>
<tr>
<td></td>
<td>Unit 7, Heritage Business Park</td>
</tr>
<tr>
<td></td>
<td>5-9 Ricketty Street, Mascot, NSW 2020</td>
</tr>
<tr>
<td><strong>EMERGENCY PHONE</strong></td>
<td>CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300</td>
</tr>
<tr>
<td></td>
<td>NSW Poisons Information Centre: 131 126</td>
</tr>
<tr>
<td></td>
<td>National Chemical Emergency Centre 44(0)1235239670</td>
</tr>
<tr>
<td><strong>USES</strong></td>
<td>Corticosteroid, Therapeutic agent</td>
</tr>
</tbody>
</table>

## SECTION 2: HAZARDS IDENTIFICATION

### GHS CLASSIFICATION
- Acute Toxicity - Oral (Category 4)
- Toxic to Reproduction (Category 2)
- Specific Target Organ Toxicity - Repeated Exposure (Category 1)

### 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 exposure (endocrine system).

### ADVERSE PHYSICOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS
- Not Applicable.

### PRECAUTIONARY STATEMENT(S)

#### Prevention
- Wash thoroughly after handling.
- 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.
SAFETY DATA SHEET

Response

IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
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
Pregn-4-ene-3,20-dione, 21-(acetyloxy)-9-fluoro-11,17-dihydroxy-, (11β)-

BOTANICAL NAME
Not applicable

SYNONYM
9-alpha-Fluorohydrocortisone acetate; Fludrocortisone 21-acetate

CHEMICAL FORMULA
C₂₃H₃₁FO₆

CAS NUMBER
514-36-3

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
422.49

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>EC NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLUDROCORTISONE ACETATE</td>
<td>514-36-3</td>
<td>208-180-4</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.

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.

SUITABLE & UNSUITABLE 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.
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.

REFERENCE TO OTHER SECTIONS
See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

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 unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE
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 unlabeled 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 well-closed containers, protected from light.

SPECIFIC END USE(S)
See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Chemical Name: FLUDROCORTISONE ACETATE</th>
<th>CAS #: 514-36-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit value-8 hours</td>
<td>IDLH</td>
</tr>
<tr>
<td>ppm</td>
<td>mg/m³</td>
</tr>
<tr>
<td>OSHA USA N/L N/L N/L N/L N/L N/L N/L N/A N/A</td>
<td></td>
</tr>
<tr>
<td>ACGIH USA N/L N/L N/L N/L N/L N/L N/L N/A N/A</td>
<td></td>
</tr>
<tr>
<td>NIOSH USA N/L N/L N/L N/L N/L N/L N/L N/A N/A</td>
<td></td>
</tr>
<tr>
<td>WEEL USA N/L N/L N/L N/L N/L N/L N/L N/A N/A</td>
<td></td>
</tr>
<tr>
<td>HSIS Australia N/L N/L N/L N/L N/L N/L N/L N/A N/A</td>
<td></td>
</tr>
<tr>
<td>HSE UK N/L N/L N/L N/L N/L N/L N/L N/A N/A</td>
<td></td>
</tr>
<tr>
<td>GESTIS Add Country N/L N/L N/L N/L N/L N/L N/L N/A N/A</td>
<td></td>
</tr>
</tbody>
</table>

N/L = Not listed ; N/A = Not Available
PELs are 8-hour TWAs = Limit value - Eight hours
Ceiling or Short-Term TWA = STEL = Limit value - Short term

Last Revision: 02/2020
FLUDROCORTISONE ACETATE, USP (Micronized)
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. Thermal Hazards: For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

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

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 pale yellow crystals or crystalline powder. Is odorless or practically odorless. Is hygroscopic.</td>
</tr>
<tr>
<td>SOLUBILITY</td>
<td>Insoluble in water; slightly soluble in ether; sparingly soluble in alcohol and in chloroform.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Odorless or Practically odorless</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td>AUTO-IGNITION TEMPERATURE</td>
<td>Not available</td>
</tr>
<tr>
<td>BOILING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE</td>
<td>(233 - 234)°C, (451.4-453.2)°F</td>
</tr>
<tr>
<td>EVAPORATION RATE</td>
<td>Not available</td>
</tr>
<tr>
<td>EXPLOSIVE LIMIT</td>
<td>Not available</td>
</tr>
<tr>
<td>FLASH POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>1.67 (20°C) (fludrocortisone)</td>
</tr>
<tr>
<td>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>MELTING/FREEZING POINT</td>
<td>(233 - 234)°C, (451.4-453.2)°F (decomposes)</td>
</tr>
<tr>
<td>ODOR THRESHOLD</td>
<td>Not available</td>
</tr>
<tr>
<td>OXIDIZING PROPERTY</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Not available</td>
</tr>
<tr>
<td>RELATIVE DENSITY (WATER = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY</td>
<td>Not available</td>
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<tr>
<td>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
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<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
<td>Not available</td>
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<tr>
<td>VAPOR PRESSURE</td>
<td>&lt; 0.0000001 kPa (25 °C)</td>
</tr>
<tr>
<td>VISCOSITY</td>
<td>Not available</td>
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</tbody>
</table>

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>
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</thead>
<tbody>
<tr>
<td>REACTIVITY</td>
<td>Not established</td>
</tr>
<tr>
<td>CHEMICAL STABILITY</td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td>INCOMPATIBLE MATERIALS</td>
<td>Strong oxidants</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>Section</td>
<td>Information</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>HAZARDOUS POLYMERIZATION</strong></td>
<td>Will not occur</td>
</tr>
<tr>
<td><strong>POSSIBILITY OF HAZARDOUS REACTION</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>CONDITIONS TO AVOID</strong></td>
<td>Moisture, sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

### SECTION 11: TOXICOLOGICAL INFORMATION

**ACUTE TOXICITY**
- Oral: Rat: LD50: (mg/kg): > 1000
- Dermal: Rabbit: LD50: (mg/kg): Not available
- Inhalation: Rat: LC50: (mg/L/4hr): Not available

**SKIN CORROSION/IRRITATION**
- Due to lack of data the classification is not possible.

**SERIOUS EYE DAMAGE/EYE IRRITATION**
- Due to lack of data the classification is not possible.

**RESPIRATORY SENSITIZATION**
- Due to lack of data the classification is not possible.

**SKIN SENSITIZATION**
- Due to lack of data the classification is not possible.

**GERM CELL MUTAGENICITY**
- Due to lack of data the classification is not possible.

**CARCINOGENICITY**
- OSHA: FLUDROCORTISONE ACETATE is not listed.
- NTP: FLUDROCORTISONE ACETATE is not listed.
- IARC: FLUDROCORTISONE ACETATE 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**
- Not available

**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.

**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.
SAFETY DATA SHEET

SIGNS AND SYMPTOMS OF EXPOSURE
Symptoms related to the physical, chemical, and toxicological characteristics:


POTENTIAL HEALTH EFFECTS
Inhalation
- May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion
- Harmful if swallowed.

Skin
- May be harmful if absorbed through skin. May cause skin irritation.

Eyes
- May cause 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
- Not available

BIOACCUMULATIVE POTENTIAL
- Log Pow: 1.67 (20°C) (fludrocortisone)

MOBILITY IN SOIL
- Insoluble 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

UN PROPER SHIPPING NAME
- Not dangerous good

UN NUMBER
- Not applicable

CLASS
- Not applicable

PACKING GROUP
- Not applicable
SAFETY DATA SHEET

AUSTRALIA

HAZCHEM
Not applicable

EU
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE
Not Listed

ENVIRONMENTAL HAZARDS
Not available

SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

<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 Appendix A</th>
<th>EPA 40 CFR Part 355 Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLUDROCORTISONE ACETATE 514-36-3</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>FLUDROCORTISONE ACETATE 514-36-3</td>
<td>Not Listed</td>
<td>Listed as Schedule 4</td>
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</tbody>
</table>

N/L = Not Listed

EU REGULATIONS

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>FLUDROCORTISONE ACETATE 514-36-3</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

Any EU regulation not listed above is not applicable to this product.

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request
ABBREVIATIONS AND ACRONYMS

- ACGIH - American Conference of Governmental Industrial Hygienists
- AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels
- CAESAR – Computer Assisted Evaluation of industrial chemical Substances According to Regulations
- CAS – Chemical Abstract Service
- CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act
- EC50 – Effective Concentration, 50%
- EPA – Environmental Protection Agency
- GHS – Global Harmonized System
- HMIS – Hazardous Materials Information System
- HSE – Health and Safety Executive
- HSIS – Hazardous Substances Information System
- IARC – International Agency for Research on Cancer
- IDLH - Immediately Dangerous to Life or Health
- IRFMN – Ready Biodegradability Model
- ISS – Instituto Superiore Sanità
- LC50 – Lethal Concentration, 50%
- LD50 – Lethal Dose, 50%
- MSHA - Mine Safety and Health Administration
- NIOSH – National Institute for Occupational Safety and Health
- NTP – National Toxicology Program
- OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits
- QSAR – Quantitative Structure-activity relationship
- REL - Recommended Exposure Limit
- SARA – Superfund Amendments and Reauthorization Act
- STEL – Short Term Exposure Limit
- TLV – Threshold Limit Value
- TWA – Time Weighted Average
- WHMIS – Workplace Hazardous Materials Information System

LAST REVISION

02/2020

SUPERSEDES

01/2016

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.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.