SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME  FLUDROCORTISONE ACETATE, USP (Micronized)
PRODUCT CODE  0129
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
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126

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).

AUSTRALIA-ONLY HAZARDS
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.
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

COMPOSITION:

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

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

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, 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. Store at 15°C - 30°C (59°F - 86°F). Preserve in well-closed containers, protected from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: FLUDROCORTISONE ACETATE    CAS #: 514-36-3

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<thead>
<tr>
<th></th>
<th>TWA</th>
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<th>STEL</th>
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</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. Fumehood, eye wash station, and safety shower.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Solid

DESCRIPTION
White to pale yellow crystals or crystalline powder. Is odorless or practically odorless. Is hygroscopic.

SOLUBILITY
Insoluble in water; slightly soluble in ether; sparingly soluble in alcohol and in chloroform.

ODOR
Odorless or Practically odorless

FLAMMABILITY
May be combustible at high temperature.
### 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): > 1000
- Dermal: Rabbit: LD50: (mg/kg): Not available
- Inhalation: Rat: LD50: (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 or 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.
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

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.

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

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

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

Symptoms related to the physical, chemical, and toxicological characteristics:

Delayed and immediate effects of exposure:
- Increase in blood pressure. Heart failure.

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

Medical conditions aggravated by exposure:

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.

EC50: 48 Hr: Daphnia magna: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (mg/L): Not available

MOBILITY IN SOIL
Insoluble in water.

TOXICITY

EC50: 48 Hr: Daphnia magna: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (mg/L): Not available

Persistency and degradability
Not available

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

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 available
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 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>
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<td>N/L</td>
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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>
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<td>Listed as Schedule 4</td>
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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

01/2016

SUPERSEDES

08/2013

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.