SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME
TRIAMCINOLONE DIACETATE, USP (Micronized)

PRODUCT CODE
2373

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

MEDISCA UK Limited
Tel.: 0800.029.4641
33 St. James's Square, London, United Kingdom SW1Y 4JS

EMERGENCY PHONE
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126
National Chemical Emergency Centre 44(0)1235239670

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Toxic to Reproduction (Category 1B)
Specific Target Organ Toxicity - Repeated Exposure (Category 1) - Endocrine System

PICTOGRAM

SIGNAL WORD
Danger

HAZARD STATEMENT(S)
May damage fertility or the unborn child.
Causes damage to organs (endocrine system) through prolonged or repeated exposure.
May cause allergic reaction.

ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS
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.
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
Pregna-1,4-diene-3,20-dione, 16,21-bis(acetyloxy)-9-fluoro-11,17-dihydroxy-, (11β,16α)-

BOTANICAL NAME
Not applicable

SYNONYM
Not applicable

CHEMICAL FORMULA
C₂₅H₃₁FO₈

CAS NUMBER
67-78-7

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
478.51

COMPOSITION
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.

Chemical family Corticosteroid. Hormone.

NOTES

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.

SUITEABLE & 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.
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.

SPECIFIC END USE(S)
See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Chemical Name: TRIAMCINOLONE DIACETATE</th>
<th>CAS #: 67-78-7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TWA</strong></td>
<td>Ceiling</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
</tr>
<tr>
<td>AIHA WEEL</td>
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<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
</tr>
<tr>
<td>GESTIS</td>
<td>N/L</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. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PHYSICAL STATE</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESCRIPTION</td>
<td>Fine, white to off-white, crystalline powder, having not more than a slight odor.</td>
</tr>
<tr>
<td>SOLUBILITY</td>
<td>Practically insoluble in water; soluble in chloroform; sparingly soluble in alcohol and in methanol; slightly soluble in ether.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Not more than a slight odor</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>536 °C, 996.8 °F</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE</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>FLASH POINT</td>
<td>300 °C, 572 °F</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>1.92</td>
</tr>
<tr>
<td>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>MELTING/FREEZING POINT</td>
<td>(186 - 188)°C, (366.8-370.4)°F</td>
</tr>
<tr>
<td>OXIDIZING PROPERTY</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
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<tr>
<td>RELATIVE DENSITY (WATER = 1)</td>
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<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>
</tr>
<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>VAPOR PRESSURE</td>
<td>2.74E-14 mm Hg (25°C)</td>
</tr>
<tr>
<td>VISCOSITY</td>
<td>Not available</td>
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</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>REACTIVITY</th>
<th>Not established</th>
</tr>
</thead>
<tbody>
<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>HAZARDOUS POLYMERIZATION</td>
<td>Will not occur</td>
</tr>
<tr>
<td>POSSIBILITY OF HAZARDOUS REACTION</td>
<td>Not established</td>
</tr>
</tbody>
</table>
SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY
- Oral: Rat: LD50: (mg/kg): Not available
- 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
Based on available data, the classification criteria are not met.

SKIN SENSITIZATION
Based on available data, the classification criteria are not met. Local reactions to topical triamcinolone preparations have been attributed to the content of ethylenediamine. However, there have also been reports of anaphylactic shock after intra-articular or intramuscular injection of triamcinolone acetonide.

GERM CELL MUTAGENICITY
TRIAMCINOLONE DIACETATE is not listed.

CARCINOGENICITY
- OSHA
  TRIAMCINOLONE DIACETATE is not listed.
- NTP
  TRIAMCINOLONE DIACETATE is not listed.
- IARC
  TRIAMCINOLONE DIACETATE 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
Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITY
May damage fertility or the unborn child. Therapeutic use of glucocorticoids during pregnancy has been associated with an increased risk of cleft palate and impaired fetal growth. Studies in a variety of animals also show an association with birth defects, including cleft palate.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Causes damage to organs (endocrine system) through prolonged or repeated exposure.

ASPIRATION HAZARDS
Due to lack of data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE
Not expected to present a significant hazard under anticipated conditions of normal use.

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

Delayed and immediate effects of exposure:

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

Medical conditions aggravated by exposure:

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

- Low: LogPow: 1.92.

#### MOBILITY IN SOIL

- Practically insoluble in water.
  - Water Solubility: 35.5 mg/L (25°C).
  - Henry's Law Constant: 1.39E-14 atm·m³/mole (25°C).

#### 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

#### UN PROPER SHIPPING NAME

- Not dangerous good

#### UN NUMBER

- Not applicable

#### CLASS

- Not applicable

#### PACKING GROUP

- Not applicable

#### AUSTRALIA

- Not applicable

#### 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
SAFETY DATA SHEET

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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</thead>
<tbody>
<tr>
<td>TRIAMCINOLONE DIACETATE 67-78-7</td>
<td>Not Listed</td>
<td>Listed as Schedule 4*</td>
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EU REGULATIONS

<table>
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<tr>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</tbody>
</table>

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

NOTES

*TRIAMCINOLONE is listed.

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS


LAST REVISION

10/2019

SUPERSEDES

12/2016

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com
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.

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