


SECTION 1: PRODUCT IDENTIFICATION

| | |
|----------------------------|--|
| PRODUCT NAME | TRIAMCINOLONE ACETONIDE, USP (Micronized) |
| PRODUCT CODE | 0011 |
| SUPPLIER | MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 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 National Chemical Emergency Centre 44(0)1235239670 |
| RECOMMENDED USES | Manufacturing and Compounding |
| RESTRICTIONS ON USE | Not applicable |

SECTION 2: HAZARDS IDENTIFICATION

| | |
|---|---|
| GHS CLASSIFICATION | Acute Toxicity - Oral (Category 4) 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. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure (endocrine system). Exposure may produce an allergic reaction. |
| ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS | Not Applicable. |

| | | | | |
|-----------------------------------|----------------------|--|----------------------------|---|
| PRECAUTIONARY STATEMENT(S) | Prevention | Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Do not breathe dust, fume, gas, mist, vapors and spray. | | |
| | Response | IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth. IF EXPOSED: Get emergency medical help immediately. Call a poison center or doctor. Get medical help 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 | 9-Fluoro-11 β , 16 α , 17, 21-tetrahydroxypregna-1, 4-diene-3, 20-dione cyclic 16, 17-acetal with acetone |
| BOTANICAL NAME | Not applicable |
| SYNONYM | Not applicable |
| CHEMICAL FORMULA | C ₂₄ H ₃₁ FO ₆ |
| CHEMICAL FAMILY | Corticosteroid. Hormone. |
| CAS NUMBER | 76-25-5 |
| ALTERNATE CAS NUMBER | Not applicable |
| MOLECULAR WEIGHT | 434.5009 |

COMPOSITION

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|-------------------------|------------|-----------|-------------|
| TRIAMCINOLONE ACETONIDE | 76-25-5 | 200-948-7 | 100 |

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 |
| MEDICAL ATTENTION AND SPECIAL TREATMENT | Get emergency medical help. |
| SYMPTOMS CAUSED BY EXPOSURE | 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.

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.

Store at 25°C. Short term excursions, temperature excursions as experienced during shipping and warehousing, are permitted between 15° - 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: TRIAMCINOLONE ACETONIDE CAS #: 76-25-5

| | Country | Limit value-8 hours | | Limit value-Short Term | | IDLH | REL | Advisory | Notes |
|------|---------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
| | | ppm | mg/m ³ | ppm | mg/m ³ | | | | |
| OSHA | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

| | | | | | | | | | |
|---------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|
| ACGIH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| NIOSH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| WEEL | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSIS | Australia | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSE | UK | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| GESTIS | Add Country | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

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

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.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

USP: TWA: 0.004 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White to cream colored, crystalline powder, having not more than a slight odor.

SOLUBILITY

Sparingly soluble in dehydrated alcohol, in chloroform, and in methanol; practically insoluble in water.

ODOR

Not more than a slight odor

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

2.53 (20 °C)

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

(292 - 294)°C,
(557.6 - 561.2)°F

PARTICLE CHARACTERISTICS

Not available

OXIDIZING PROPERTY

Not available

pH

Not available

RELATIVE DENSITY (WATER = 1)

Not available

SPECIFIC GRAVITY

Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

**VAPOR DENSITY
(AIR = 1)**

Not available

VAPOR PRESSURE

 < 0.0000001 kPa
(25 °C)

VISCOSITY

Not available

The physical data presented above are typical values and should not be construed as a specification.



SECTION 10: STABILITY AND REACTIVITY

REACTIVITY

Not established

CHEMICAL STABILITY

Stable under recommended storage conditions

INCOMPATIBLE MATERIALS

Strong oxidants and reducing agents.

**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. Light sensitive.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

 Oral: Rat: LD50: (mg/kg): 1451
 Dermal: Rabbit: LD50: (mg/kg): Not available
 Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

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

**SERIOUS EYE DAMAGE/EYE
IRRITATION**

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

RESPIRATORY SENSITIZATION

Due to lack of data the classification is not possible.

SKIN SENSITIZATION

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

GERM CELL MUTAGENICITY

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

CARCINOGENICITY
OSHA TRIAMCINOLONE ACETONIDE is not listed.

NTP TRIAMCINOLONE ACETONIDE is not listed.

IARC TRIAMCINOLONE 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.

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.
 Fertility study: Rat: Oral: 15 microgram/kg: No adverse effect.
 Reproductivity and development study: Monkey: 2.5 mg/kg: Fetal loss of 71%; high incidence of cranial defects in recovered fetuses.
 Reproductivity and development study: Rabbit: Inhalation: 20 microgram/kg: Teratogenic.
 Reproductivity and development study: Rat: Inhalation: 20 microgram/kg: Teratogenic.
 Reproductivity and development study: Rat: Oral: 5 microgram/kg: Fetotoxic
 Reproductivity and development study: Monkey: Inhalation: 500 microgram/kg: Teratogenic

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

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

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

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
ASPIRATION HAZARDS

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

SIGNS AND SYMPTOMS OF EXPOSURE

ROUTES OF EXPOSURE:
 Oral, Dermal, Inhalation, Eye contact
EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:
 Not available
DELAYED HEALTH EFFECT FROM EXPOSURE:
 Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression. Immune system depression. Withdrawal.

Symptoms related to the physical, chemical, and toxicological characteristics:
 Mineralocorticoid effects: Swelling. Confusion. Lightheadedness. Nausea. Vomiting. Numbness. Tremors.
 Glucocorticoid effects: Bone fractures. Back pain. Joint pain or stiffness. Weakness. Increased appetite. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Increased hair growth. Acne. Redistribution of body fat. Menstrual irregularities. Impotence. Headache. Increased sweating. Eye pain. Change in vision. Mental or behavioral changes. Withdrawal effects: Fever. Muscle pain. Joint pain. Malaise.

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 | Harmful if swallowed. |
| Skin | May be harmful if absorbed through skin. May cause skin irritation. |
| Eyes | May cause eye irritation. |

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

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: 2.53 (20 °C)
 Bioaccumulative potential 4. Weak.

MOBILITY IN SOIL

Practically insoluble in water. Water Solubility: 21 mg/L (28 °C).
 Henry's Law Constant: 9.83E-13 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
DISPOSAL METHODS

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
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

| Chemical Name & CAS | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Part 372.65 | EPA 40 CFR Part 355 Appendix A | EPA 40 CFR Part 355 Appendix B | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|---------------------------------|--------------------------|-------------------------------------|--------------------------------|--------------------------------|--------------|--------------------------|---------------|--------------------|
| TRIAMCINOLONE ACETONIDE 76-25-5 | N/L | N/L | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

| Chemical Name & CAS | Poisons and Therapeutic Goods | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|---------------------------------|-------------------------------|-----------------------|---|------------------|------------------------------------|-----------------------------------|
| TRIAMCINOLONE ACETONIDE 76-25-5 | N/L | Listed as Schedule 4* | N/L | Listed* | N/L | N/L |

N/L = Not Listed

EU REGULATIONS

| Chemical Name & CAS | REACH ANNEX XVII | REACH ANNEX XIV | EC 1005/2009 | EC 850/2004 | EC 1107/2009 | PIC - Prior Informed Consent Regulation | EC 2012/18 |
|---------------------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| TRIAMCINOLONE ACETONIDE 76-25-5 | N/L | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

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

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

NOTES *TRIAMCINOLONE is listed.

SECTION 16: OTHER INFORMATION

REFERENCES

ABBREVIATIONS AND ACRONYMS

Available upon request

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** – Istituto 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

11/2023

SUPERSEDES

04/2021

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

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.