


SECTION 1: PRODUCT IDENTIFICATION

| | |
|----------------------------|--|
| PRODUCT NAME | MOMETASONE FUROATE, USP |
| PRODUCT CODE | 2413 |
| SUPPLIER | MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 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 | Pharmaceutical Manufacturing |
| RESTRICTIONS ON USE | Not applicable |

SECTION 2: HAZARDS IDENTIFICATION

| | |
|---|--|
| GHS CLASSIFICATION | Acute Toxicity - Oral (Category 5) Toxic to Reproduction (Category 2) Chronic Aquatic Toxicity (Category 2) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (endocrine system) |
| PICTOGRAM |  |
| SIGNAL WORD | Danger |
| HAZARD STATEMENT(S) | May be harmful if swallowed. May cause an allergic reaction. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure (endocrine system). Toxic to aquatic life with long lasting effects |
| ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS | Not Applicable. |

PRECAUTIONARY STATEMENT(S)
Prevention

Do not breathe dust/fume/gas/mist/ vapors/spray.
Contaminated work clothing should not be allowed out of the workplace.
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.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Avoid release to the environment.

Response

IF SWALLOWED: Get medical help.
IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
IF EXPOSED OR CONCERNED: Get medical advice.
Get medical help if you feel unwell.
COLLECT SPILLAGE

Storage

Store locked up.

Disposal

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

HMS CLASSIFICATION
Health Hazard

1

Flammability

0

Reactivity

0

Personal Protection

G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME

Pregna-1, 4-diene-3, 20-dione, 9, 21-dichloro-17-[(2-furanylcarbonyl) oxy]-11-hydroxy-16-methyl-, (11β, 16α)-.

BOTANICAL NAME

Not applicable

SYNONYM

Not applicable

CHEMICAL FORMULA

C₂₇H₃₀Cl₂O₆

CHEMICAL FAMILY

Corticosteroid

CAS NUMBER

83919-23-7

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

521.43

COMPOSITION

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|--------------------|------------|-----------|-------------|
| MOMETASONE FUROATE | 83919-23-7 | 617-501-0 | 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.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: MOMETASONE FUROATE CAS #: 83919-23-7

| | 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

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
**PHYSICAL
STATE**

Solid

DESCRIPTION

White to off-white powder.

SOLUBILITY

Practically insoluble in water; freely soluble in alcohol and in acetone; sparingly soluble in propylene glycol.

ODOR

Odorless

| | | | | | |
|-------------------------------------|--|---|---------------|---|-----------------------------------|
| 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) | 4.115 (20°C) | LOWER FLAMMABLE/EXPLOSIVE LIMIT(S) | Not available | MELTING/FREEZING POINT | (218 - 220)°C, (424.4 - 428)°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 | Not available | 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. |
| 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): >2000 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

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

Suspected skin sensitiser: 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.

Rat hepatocytes Mutagenicity, In vivo unscheduled DNA synthesis assay: Result: Positive

Suspected mutagen: The Toolbox profiler in vitro mutagenicity (Ames test) alerts by ISS gives an alert for mutagenicity; The Toolbox profiler Protein binding alerts for Chromosomal aberration by OASIS v1.1 gives an alert for mutagenicity

CARCINOGENICITY

OSHA MOMETASONE FUROATE is not listed.

NTP MOMETASONE FUROATE is not listed.

IARC MOMETASONE FUROATE is not evaluated.

California Proposition 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; ISS Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (good reliability).

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. Corticosteroids have been shown to cause birth defects in laboratory animals when administered systemically at low doses, and some caused birth defects when administered topically.

Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (moderate reliability).

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

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

Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea.

Skin

May cause skin irritation. May cause allergic reaction. Mometasone Furoate can be absorbed through intact skin. Symptoms of chronic overexposure by this route may include reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine.

Eyes

May cause eye irritation.

NOTES

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available

LC50: 96 Hr: Fish: (mg/L): < 1*

EC50: 96 Hr: Green algae: (mg/L): < 1*

**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

High: LogPow: 4.115 (20°C)

MOBILITY IN SOIL

Practically insoluble in water. (< 1 mg/L)

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment.

NOTES

*Danish QSAR database

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 | EPA 40 CFR Part 355 | | Pennsylvania | Right-to-know | | California Prop 65 |
|----------------------------------|--------------------------------|-------------------------------|---------------------|------------|--------------|---------------|---------------|-----------------------|
| | | | Appendix A | Appendix B | | New Jersey | Massachusetts | |
| MOMETASONE FUROATE 83919-23-7 | 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 | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|----------------------------------|-------------------------------------|--------------------------|--|---------------------|--|---|
| MOMETASONE FUROATE 83919-23-7 | 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 |
|----------------------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| MOMETASONE FUROATE 83919-23-7 | 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 *Listed as the base

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** – 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

03/2024

SUPERSEDES

05/2023

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.