

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 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
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Corticosteroid (Topical); Anti-Inflammatory Agent; Anti-allergic Agent

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)
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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.
 Toxic to aquatic life with long lasting effects

AUSTRALIA-ONLY HAZARDS

Not Applicable.

PRECAUTIONARY STATEMENT(S)

Prevention	Do not breathe dust/fume/gas/mist/ vapors/spray. Contaminated work clothing must not be allowed out of the workplace. 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. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment.
Response	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/attention. COLLECT SPILLAGE
Storage	Store locked up.

HMIS CLASSIFICATION	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	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-, (11 β , 16 α)-.
BOTANICAL NAME	Not applicable
SYNONYM	Not applicable
CHEMICAL FORMULA	C ₂₇ H ₃₀ Cl ₂ O ₆
CAS NUMBER	83919-23-7
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	521.434

CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
MOMETASONE FUROATE	83919-23-7	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.

NOTES
Chemical family: Corticosteroid.

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.
EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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. 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 unlabelled 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.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

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.

NOTES

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

YOUR TRUSTED PARTNER IN COMPOUNDING

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 combustibile at high temperature				
ODOR THRESHOLD	Not available	pH	Not available	MELTING POINT	(215 - 228)°C, (419-442.4)°F
BOILING POINT	Not available	FREEZING POINT	(215 - 228)°C, (419-442.4)°F	FLASH POINT	Not available
SPECIFIC GRAVITY	Not available	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	Not available
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	4.115 (20°C)
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

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

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): >2000 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 OR SKIN SENSITIZATION

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 sensitizer: The Toolbox profiler Protein binding alerts for skin sensitization by OASIS v1.3 gives an alert for skin sensitization

GERM CELL MUTAGENICITY

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

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 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.

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

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.

SIGNS AND SYMPTOMS OF EXPOSURE

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

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.

Delayed and immediate effects of exposure:

Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression. Immune system depression. Withdrawal.

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.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	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
NOTES	This product is not intended to be released into the environment. *Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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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
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SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
MOMETASONE FUROATE 83919-23-7	N/L	Listed as Schedule 4	N/L

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

11/2018

SUPERSEDES

07/2015

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.