


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	BETAMETHASONE SODIUM PHOSPHATE, USP
PRODUCT CODE	0195
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 (glucocorticoid); Anti-Inflammatory Agent

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4) Toxic to Reproduction (Category 2) Chronic Aquatic Toxicity (Category 2) Eye Irritation (Category 2B) 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 Causes eye irritation Toxic to aquatic life with long lasting effects. May cause allergic reaction May be fatal if inhaled
AUSTRALIA-ONLY HAZARDS	Not Applicable.
PRECAUTIONARY STATEMENT(S)	Prevention <ul style="list-style-type: none"> 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. Avoid release to the environment

HMIS CLASSIFICATION	Response	IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth. IF EXPOSED OR CONCERNED: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. COLLECT SPILLAGE		
	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy)-, disodium salt, (11 β ,16 β)
BOTANICAL NAME	Not applicable
SYNONYM	Betamethasone 21-phosphate disodium salt; Betamethazone disodium phosphate
CHEMICAL FORMULA	C ₂₂ H ₂₈ FN ₂ O ₈ P
CAS NUMBER	151-73-5
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	516.4072

CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
BETAMETHASONE SODIUM PHOSPHATE	151-73-5	100

COMPOSITION	
NOTES	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.

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, 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. 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 tight containers, protected from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: **BETAMETHASONE SODIUM PHOSPHATE** CAS #: 151-73-5

	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				
DESCRIPTION	White to practically white, odorless powder. Is hygroscopic.				
SOLUBILITY	Freely soluble in water and in methanol; practically insoluble in acetone and in chloroform.				
ODOR	Odorless				
FLAMMABILITY	May be combustible at high temperature				
ODOR THRESHOLD	Not available	pH	7.5 - 9 (1%)	MELTING POINT	Not available
BOILING POINT	Not available	FREEZING POINT	Not available	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	< 0.000001 kPa (25°C)
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	4.07 (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	Acids. Bases. Oxidizing agents. 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.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	<p>Oral: Rat: LD50: (mg/kg): 1877 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available</p>
SKIN CORROSION/IRRITATION	<p>Based on available data, the classification criteria are not met. Skin irritancy, Result: Non-irritating. Species: Rabbit.</p>
SERIOUS EYE DAMAGE/EYE IRRITATION	<p>Causes eye irritation. Eye irritancy, Result: Mild, reversible ocular irritation; reversible at 7 days. Species: Rabbit.</p>
RESPIRATORY OR SKIN SENSITIZATION	<p>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 carcinogen: The Toolbox profiler Carcinogenicity (genotox and nongenotox) alerts by ISS gives an alert for carcinogenicity.</p>
GERM CELL MUTAGENICITY	<p>Due to lack of data the classification is not possible. Suspected mutagen: The Toolbox profiler Protein binding alerts for Chromosomal aberration by OASIS v1.1 gives an alert for mutagenicity</p>
CARCINOGENICITY	<p>OSHA BETAMETHASONE SODIUM PHOSPHATE is not listed. NTP BETAMETHASONE SODIUM PHOSPHATE is not listed. IARC BETAMETHASONE SODIUM PHOSPHATE 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.</p>
ADDITIONAL CARCINOGENICITY INFORMATION	<p>Due to lack of data the classification is not possible.</p>
REPRODUCTIVE TOXICITY	<p>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. Species: Rabbit: 0.05 mg/kg Developmental study (Betamethasone dipropionate) Result: Birth defects included umbilical hernia, cephalocele, and cleft palate. Species: Rabbit: 1 mg/kg Reproductive study (Betamethasone dipropionate) Result: Dose-related increases in fetal resorption. Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction.</p>
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	<p>Due to lack of data the classification is not possible.</p>
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	<p>Causes damage to organs (endocrine system, immune system suppression) through prolonged or repeated exposure.</p>
ASPIRATION HAZARDS	<p>Based on available data, the classification criteria are not met.</p>
SIGNS AND SYMPTOMS OF EXPOSURE	<p>Symptoms related to the physical, chemical, and toxicological characteristics: Corticosteroids: Nausea. Vomiting. Headache. Acne. Increased hair growth. Lightheadedness. Weakness. Increased sweating. Eye pain. Vision changes. Mental or behavioral changes. Swelling. Numbness. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Bone fractures. Back pain. Joint pain or stiffness. Increased appetite. Redistribution of body fat. Menstrual irregularities. Impotence. Tremors. 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</p>

POTENTIAL HEALTH EFFECTS	Inhalation	May be fatal if inhaled. May cause respiratory tract irritation.
	Ingestion	Harmful if swallowed.
	Skin	May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.
	Eyes	Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 1.9 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	Biodegradation: 28 % (Minimally biodegradable). Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable
BIOACCUMULATIVE POTENTIAL	LogPow: 4.07 (20°C)
MOBILITY IN SOIL	Freely soluble in water.
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.
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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
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	
BETAMETHASONE SODIUM PHOSPHATE 151-73-5	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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
BETAMETHASONE SODIUM PHOSPHATE 151-73-5	N/L	Listed as Schedule 4*	N/L

NOTES

*Listed as Betamethasone

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

11/2018

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.