


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	PREDNISOLONE, USP (Anhydrous) (Micronized)
PRODUCT CODE	0150
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	Toxic to Reproduction (Category 2) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (Endocrine system) Acute Toxicity - Oral (Category 5)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure. May cause an allergic reaction. Toxic to aquatic life with long lasting effects. May be harmful if swallowed.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable

PRECAUTIONARY STATEMENT(S)	Prevention	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/spray.		
	Response	IF EXPOSED OR CONCERNED: Get medical advice. IF SWALLOWED: Get medical help		
	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
HMS CLASSIFICATION	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	(11-Beta)-11,17,21-trihydroxypregna-1,4-diene-3,20-dione
BOTANICAL NAME	Not applicable
SYNONYM	1-Dehydrohydrocortisone
CHEMICAL FORMULA	C ₂₁ H ₂₈ O ₅
CHEMICAL FAMILY	Corticosteroid
CAS NUMBER	50-24-8
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	360.4472

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
PREDNISOLONE (Anhydrous)	50-24-8	200-021-7	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

Combustion products CO, CO₂, NO_x, hydrogen chloride, phosgene, other pyrolysis products and typical burning organic material.

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: PREDNISOLONE (Anhydrous) CAS #: 50-24-8

	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	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

OEL (supplier data): 0.05 mg/m³

USP: ELV: Industrial use: TWA: 4 micrograms/m³ (skin notation)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

White to practically white, odorless, crystalline powder. Is hygroscopic.

SOLUBILITY

Very slightly soluble in water; soluble in methanol and in dioxane; sparingly soluble in acetone and in alcohol; slightly soluble in chloroform.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

(237-239)°C,
(458.6-462.2)°F

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)	1.62	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	235 °C, 455 °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	< 0.000001 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
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. Hygroscopic - Avoid exposure to moisture.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 3857 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. Skin irritancy test, In vitro membrane barrier test (OECD 435): Negative. Rabbit: Skin irritation; Result: Negative.
SERIOUS EYE DAMAGE/EYE IRRITATION	Based on available data, the classification criteria are not met. Rabbit: Eye irritation; Result: Negative.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Based on available data, the classification criteria are not met. Species: Mouse: (OECD 429) : Result: Does not cause skin sensitisation. There are reports of hypersensitivity and anaphylaxis following corticosteroid exposure.
GERM CELL MUTAGENICITY CARCINOGENICITY	Due to lack of data the classification is not possible.
OSHA	PREDNISOLONE is not listed.

ADDITIONAL CARCINOGENICITY INFORMATION	<p>NTP PREDNISOLONE is not listed.</p> <p>IARC PREDNISOLONE is not evaluated.</p> <p>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.</p> <p>Based on available data, the classification criteria are not met.</p> <p>Long-term carcinogenicity study, administered in drinking water: Rat: 2 years: 0.368 mg/kg/day: Increased incidence of hepatic tumors.</p> <p>Long-term carcinogenicity study, administered orally: Rat: 18 months: 3 mg/kg: 1 to 9 times per month: No increase in the incidence of tumors.</p>
REPRODUCTIVE TOXICITY	<p>Suspected of damaging fertility or the unborn child.</p> <p>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.</p> <p>Prenatal developmental toxicity study, administered subcutaneously during gestation: Rat: 12.5 - 100 mg/kg/day: Increased incidence of cleft palate at the high dose.</p> <p>Based on available data, the classification criteria are not met.</p>
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	<p>Causes damage to organs (endocrine system) through prolonged or repeated exposure.</p>
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	<p>Based on available data, the classification criteria are not met.</p>
ASPIRATION HAZARDS	<p>Based on available data, the classification criteria are not met.</p>
SIGNS AND SYMPTOMS OF EXPOSURE	<p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available</p> <p>DELAYED HEALTH EFFECT FROM EXPOSURE: Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression. Immune system depression. Withdrawal.</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics: Corticosteroids: Fluid and electrolyte imbalance. Adrenal suppression. Immunosuppression. Cushing's syndrome. High blood pressure. Gastrointestinal disturbances. Headache. Lightheadedness. Weakness. Visual disturbances. Mood or mental status changes. Infection. Thinning skin. Swelling. Bruising. Bone fractures. Back pain. Joint pain. Tremors. Menstrual irregularities. Impotence.</p> <p>Cross sensitivity: Persons sensitive to one corticosteroid may be sensitive to this material also.</p> <p>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	<p>Inhalation May be harmful if inhaled. May cause respiratory tract irritation.</p> <p>Ingestion May be harmful if swallowed.</p> <p>Skin May be harmful if absorbed through skin. May cause skin irritation</p> <p>Eyes May cause eye irritation.</p>
NOTES	<p>Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.</p>

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish (Ide, silver or golden orfe (Leuciscus idus)): (mg/L): > 500 EC50: 72 Hr: Pseudokirchneriella subcapitata (green algae): (mg/L):160*
PERSISTENCE AND DEGRADABILITY	Good biodegradability: > 95%. Readily biodegradable.
BIOACCUMULATIVE POTENTIAL	Log Pow = 1.62
MOBILITY IN SOIL	Henry's Law Constant: 2.71E-08atm-m ³ /mole (25°C). Water Solubility: 223 mg/L (25°C).
OTHER ADVERSE EFFECTS	Not available
NOTES	This product is not intended to be released into the environment *OECD Test Guideline 201

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

<u>AUSTRALIA</u>	
HAZCHEM	Not applicable

<u>EU</u>	
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 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
PREDNISOLONE (Anhydrous) 50-24-8	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
PREDNISOLONE (Anhydrous) 50-24-8	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
PREDNISOLONE (Anhydrous) 50-24-8	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

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

07/2024

SUPERSEDES

08/2023

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.