


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>DEXAMETHASONE ACETATE, USP (Anhydrous)(Micronized)</b>
<b>PRODUCT CODE</b>	<b>1905</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	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
<b>RECOMMENDED USES</b>	Pharmaceutical Manufacturing
<b>RESTRICTIONS ON USE</b>	Not applicable

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Toxic to Reproduction (Category 2) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (endocrine system)	
<b>PICTOGRAM</b>		
<b>SIGNAL WORD</b>	Danger	
<b>HAZARD STATEMENT(S)</b>	Harmful if swallowed or inhaled Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure. Suspected of causing cancer.	
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not applicable	
<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>	Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/ vapors/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Wear protective gloves, protective clothing, eye and face protection and hearing protection.

HMIS CLASSIFICATION	<b>Response</b>	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: Get emergency medical help immediately. Call a poison center or doctor.		
	<b>Storage</b>	Store locked up.		
	<b>Disposal</b>	Dispose of contents and/or container in accordance with local regulations.		
	<b>Health Hazard</b>	2	<b>Flammability</b>	0
	<b>Reactivity</b>	0	<b>Personal Protection</b>	G

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>CHEMICAL NAME</b>	9-fluoro-11 $\beta$ , 17, 21-trihydroxy-16 $\alpha$ -methylpregna-1, 4-diene-3, 20-dione 21-acetate
<b>BOTANICAL NAME</b>	Not applicable
<b>SYNONYM</b>	Dexamethasone 21-acetate
<b>CHEMICAL FORMULA</b>	C <sub>24</sub> H <sub>31</sub> FO <sub>6</sub>
<b>CHEMICAL FAMILY</b>	Corticosteroid
<b>CAS NUMBER</b>	1177-87-3
<b>ALTERNATE CAS NUMBER</b>	Not applicable
<b>MOLECULAR WEIGHT</b>	434.51

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
DEXAMETHASONE ACETATE (Anhydrous)	1177-87-3	214-646-8	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

<b>IN CASE OF EYE CONTACT</b>	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
<b>IN CASE OF SKIN CONTACT</b>	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
<b>IF SWALLOWED</b>	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
<b>IF INHALED</b>	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
<b>MEDICAL ATTENTION AND SPECIAL TREATMENT</b>	Get emergency medical help.
<b>SYMPTOMS CAUSED BY EXPOSURE</b>	Not expected to present a significant hazard under anticipated conditions of normal use.

### SECTION 5: FIREFIGHTING MEASURES

<b>SPECIFIC HAZARDS ARISING FROM THE CHEMICAL</b>	Not applicable
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**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, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, 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 in original container, tightly sealed container, protected from direct sunlight, in a dry, and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store at 25, excursions permitted between 15° and 30°.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

Chemical Name: DEXAMETHASONE ACETATE (Anhydrous) CAS #: 1177-87-3

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

<b>ACGIH</b>	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>NIOSH</b>	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>WEEL</b>	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>HSIS</b>	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>HSE</b>	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>GESTIS</b>	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/m<sup>3</sup>

#### 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

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL STATE

Solid

#### DESCRIPTION

Clear, white to off-white, odorless powder.

#### SOLUBILITY

Practically insoluble in water; freely soluble in methanol, in acetone, and in dioxane.

#### 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)

2.91

#### LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

#### MELTING/FREEZING POINT

(238 - 240)°C,  
(460.4-464)°F

#### PARTICLE CHARACTERISTICS

Not available

#### OXIDIZING PROPERTY

Not available

#### pH

Not available

<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	< 0.000001 kPa (25°C)	<b>VISCOSITY</b>	Not available

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

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions
<b>INCOMPATIBLE MATERIALS</b>	Strong oxidants
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established
<b>CONDITIONS TO AVOID</b>	Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): Not available Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Due to lack of data the classification is not possible.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Due to lack of data the classification is not possible.
<b>RESPIRATORY SENSITIZATION</b>	Due to lack of data the classification is not possible.
<b>SKIN SENSITIZATION</b>	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.
<b>GERM CELL MUTAGENICITY</b>	Based on available data, the classification criteria are not met. Suspected mutagen: The Toolbox profiler Protein binding alerts for Chromosomal aberration by OASIS v1.1 gives an alert for mutagenicity.
<b>CARCINOGENICITY</b>	<b>OSHA</b> DEXAMETHASONE ACETATE is not listed. <b>NTP</b> DEXAMETHASONE ACETATE is not listed. <b>IARC</b> DEXAMETHASONE ACETATE is not evaluated. <b>California Proposition</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	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.

**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. Epidemiological studies have not shown an association between therapeutic use of the base during pregnancy and an increased incidence of birth defects. Reproductivity studies in animals administered the base have shown maternal and fetal toxicity and teratogenicity.  
 Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction.

**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**
**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:**

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. Mineralocorticoid effects: Swelling. Confusion. Light-headedness. Nausea. Vomiting. Numbness. Tremors. Withdrawal effects: Fever. Muscle pain. Joint pain. Malaise.

**Cross sensitivity:**

Persons sensitive to other corticosteroids may also be sensitive to this material.

**Medical conditions aggravated by exposure:**

History of malaria. Tuberculosis. Myasthenia gravis. 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**

<b>Inhalation</b>	Harmful if inhaled. May cause upper respiratory tract irritation.
<b>Ingestion</b>	Harmful if swallowed.
<b>Skin</b>	May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.
<b>Eyes</b>	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

<b>PERSISTENCE AND DEGRADABILITY</b>	Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.
<b>BIOACCUMULATIVE POTENTIAL</b>	LogPow: 2.91
<b>MOBILITY IN SOIL</b>	Water Solubility: 5.47 mg/L (25°C) Henry's Law Constant: 7.73E-12 atm-m <sup>3</sup> /mole (25°C)
<b>OTHER ADVERSE EFFECTS</b>	Not available

This product is not intended to be released into the environment

## SECTION 13: DISPOSAL CONSIDERATIONS

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

<b>UN PROPER SHIPPING NAME</b>	Not dangerous good
<b>UN NUMBER</b>	Not applicable
<b>CLASS</b>	Not applicable
<b>PACKING GROUP</b>	Not applicable

<b>AUSTRALIA HAZCHEM</b>	Not Applicable
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<b>EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b>	Not listed
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<b>ENVIRONMENTAL HAZARDS</b>	Not available
<b>SPECIAL SHIPPING INFORMATION</b>	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	
DEXAMETHASONE ACETATE 1177-87-3	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS



**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.