

## SECTION 1: PRODUCT IDENTIFICATION

**PRODUCT NAME**

HYDROCORTISONE ACETATE, USP (Micronized)

**PRODUCT CODE**

0008

**SUPPLIER**

**MEDISCA Inc.**

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**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

**USES**

Glucocorticoid

## SECTION 2: HAZARDS IDENTIFICATION

**GHS CLASSIFICATION**

Toxic to Reproduction (Category 2)  
Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (endocrine system)

**PICTOGRAM**



**SIGNAL WORD**

Danger

**HAZARD STATEMENT(S)**

Suspected of damaging fertility or the unborn child  
Causes damage to organs through prolonged or repeated exposure  
May cause allergic reaction

**ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS**

Repeated exposure may cause skin dryness or cracking.

**PRECAUTIONARY STATEMENT(S)**

**Prevention**  
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.

**Response** IF EXPOSED OR CONCERNED: Get medical advice/attention if you feel unwell.

**Storage** Store locked up.

HMIS CLASSIFICATION	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	Pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy-, (11 $\beta$ )-											
BOTANICAL NAME	Not applicable											
SYNONYM	Hydrocortisone-21-acetate; Cortisol, 21-acetate											
CHEMICAL FORMULA	C <sub>23</sub> H <sub>32</sub> O <sub>6</sub>											
CAS NUMBER	50-03-3											
ALTERNATE CAS NUMBER	Not applicable											
MOLECULAR WEIGHT	404.50											
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>HYDROCORTISONE ACETATE</td> <td>50-03-3</td> <td>200-004-4</td> <td>100</td> </tr> </tbody> </table>				CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	HYDROCORTISONE ACETATE	50-03-3	200-004-4	100
CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT									
HYDROCORTISONE ACETATE	50-03-3	200-004-4	100									
NOTES	<p>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.</p> <p>Chemical family: Corticosteroid.</p>											

### 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.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	<b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> 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 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. Preserve in well-closed containers, protected from light.

### SPECIFIC END USE(S)

See Section 1

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: HYDROCORTISONE ACETATE CAS #: 50-03-3

	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
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	N/A	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.

**NOTES**

USP: ELV: Industrial use: TWA: 0.5 mg/m<sup>3</sup> and 20 micrograms/m<sup>3</sup> (skin)

Manufacturer's OEL: TWA: 8hr: 100 micrograms/m<sup>3</sup> (skin)

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE**

Solid

**DESCRIPTION**

White to practically white, odorless, crystalline powder.

**SOLUBILITY**

Insoluble in water; slightly soluble in alcohol and in chloroform.

**ODOR**

Odorless

**FLAMMABILITY**

May be combustible at high temperature

**AUTO-IGNITION TEMPERATURE**

Not available

**BOILING POINT**

Not available

**DECOMPOSITION TEMPERATURE**

223 °C, 433.4 °F

**EVAPORATION RATE**

Not available

**EXPLOSIVE LIMIT**

Not available

**FLASH POINT**

Not available

**log P (OCTANOL-WATER)**

3.8 (20 °C)

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

Not available

**MELTING/FREEZING POINT**

(216 - 225)°C, (420.8-437)°F

**ODOR THRESHOLD**

Not available

**OXIDIZING PROPERTY**

Not available

**pH**

5.5 - 7.5

**RELATIVE DENSITY (WATER = 1)**

Not available

**SPECIFIC GRAVITY**

1.289

**UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)**

Not available

**VAPOR DENSITY (AIR = 1)**

Not available

**VAPOR PRESSURE**

2.56E-13 mm Hg (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**

Bases. Strong acids. Strong oxidizing agents.

**HAZARDOUS DECOMPOSITION PRODUCTS**

Toxic fumes of carbon monoxide, carbon dioxide 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): 5000  
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. Hypersensitivity reactions have occurred with corticosteroids, mainly when applied topically.

**GERM CELL MUTAGENICITY**

Due to lack of data the classification is not possible.

**CARCINOGENICITY**

**OSHA** HYDROCORTISONE ACETATE is not listed.

**NTP** HYDROCORTISONE ACETATE is not listed.

**IARC** HYDROCORTISONE ACETATE 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.

**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 hypoadrenalinism. A related material has caused birth defects in animals.  
Reproductive & Fertility Rat Oral 0.4 mg/kg/day LOAEL Fetotoxicity  
Embryo / Fetal Development Rat Oral 1 g/kg LOEL Teratogenic

**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

Symptoms related to the physical, chemical, and toxicological characteristics  
 Mineralocorticoid effects: Swelling. Confusion. Light-headedness. 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

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

## SECTION 12: ECOLOGICAL INFORMATION

### TOXICITY

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

### PERSISTENCE AND DEGRADABILITY

Readily biodegradable.

### BIOACCUMULATIVE POTENTIAL

LogPow: 3.8

### MOBILITY IN SOIL

Insoluble in water

Henry's Law Constant: 6.24E-12 atm-m<sup>3</sup>/mol (25°C)

### 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.

## 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 available

## 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 Part 372.65	EPA 40 CFR Part 355 Appendix A      Appendix B		Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
HYDROCORTISONE ACETATE 50-03-3	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
HYDROCORTISONE ACETATE 50-03-3	N/L	Listed as Schedule 4	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	EC 649/2012	EC 2012/118
HYDROCORTISONE ACETATE 50-03-3	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.

## SECTION 16: OTHER INFORMATION

### REFERENCES

Available upon request



# SAFETY DATA SHEET

## 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** – Instituto 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

02/2020

## SUPERSEDES

09/2016

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://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.