


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>SPIRONOLACTONE, USP/EP</b>
<b>PRODUCT CODE</b>	<b>0096</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>	Acute Toxicity - Oral (Category 4) Carcinogenicity (Category 2) Toxic to Reproduction (Category 2) Chronic Aquatic Toxicity (Category 4) Specific Target Organ Toxicity - Repeated Exposure (Category 2)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Warning
<b>HAZARD STATEMENT(S)</b>	Harmful if swallowed. May cause an allergic reaction. Suspected of causing cancer. Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure. May cause long lasting harmful effects to aquatic life.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Applicable.

**PRECAUTIONARY STATEMENT(S)**
**Prevention**

Wash thoroughly after handling.  
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.  
Contaminated work clothing should not be allowed out of the workplace.  
Avoid release to the environment.

**Response**

IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth.  
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.  
Get medical help if you feel unwell

**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**

1

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**
**CHEMICAL NAME**

Pregn-4-ene-21-carboxylic acid, 7-(acetylthio)-17-hydroxy-3-oxo-,  $\gamma$ -lactone (7 $\alpha$ , 17 $\alpha$ -)

**BOTANICAL NAME**

Not applicable

**SYNONYM**

Not applicable

**CHEMICAL FORMULA**

C<sub>24</sub>H<sub>32</sub>O<sub>4</sub>S

**CHEMICAL FAMILY**

Synthetic steroid

**CAS NUMBER**

52-01-7

**ALTERNATE CAS NUMBER**

Not applicable

**MOLECULAR WEIGHT**

416.5788

**COMPOSITION**

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
SPIRONOLACTONE	52-01-7	200-133-6	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

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

**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 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: SPIRONOLACTONE CAS #: 52-01-7**

	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	24:32.20 mineralocorticoid receptor antagonists	FDA Pregnancy Category C; Black Box warning for tumorigenicity in laboratory studies
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	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

**NOTES**

 USP: ELV: Industrial: TWA: 90 micrograms/m<sup>3</sup>
**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White or light cream-colored to light tan, crystalline powder. Has a faint to mild mercaptan-like odor.

**SOLUBILITY**

Practically insoluble in water; freely soluble in benzene and in chloroform; soluble in ethyl acetate and in alcohol; slightly soluble in methanol and in fixed oils.

**ODOR**

Mild characteristic odor

**FLAMMABILITY**

May be combustible at high temperature

<b>AUTO-IGNITION TEMPERATURE</b>	Not available	<b>BOILING POINT</b>	134 °C, 273.2 °F	<b>DECOMPOSITION TEMPERATURE</b>	(198-209)°C, (388.4-408.2)°F (resolidifies and decomposes)
<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	Not available
<b>log P (OCTANOL-WATER)</b>	3.56 (20°C)	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(134 - 135)°C, (273.2-275)°F
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	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>	< 0.0000001 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): >1000 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.

**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.

**CARCINOGENICITY**

**OSHA** SPIRONOLACTONE is not listed.

**NTP** SPIRONOLACTONE is not listed.

**IARC** SPIRONOLACTONE is listed in group 3 (not classifiable as to its carcinogenicity to humans).

**California Proposition** This product contains the following chemical known to the State of California to cause cancer: SPIRONOLACTONE.

**ADDITIONAL CARCINOGENICITY  
INFORMATION**

Orally administered spironolactone has been shown to be a tumorigen in dietary administration studies performed in rats, with its proliferative effects manifested on endocrine organs and the liver.

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.

Rat: 40 mg/day Reproductivity; Result: Feminization of the male fetus occurred.

Mouse: 80 mg/kg Reproductivity; Result: No birth defects, but resorptions were seen.

**SPECIFIC TARGET ORGAN  
TOXICITY - SINGLE EXPOSURE**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN  
TOXICITY - REPEATED  
EXPOSURE**

May cause damage to organs 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:**

Not available

Symptoms related to the physical, chemical, and toxicological characteristics:

Increased urination. Confusion. Irregular heartbeat. Numbness, pain, tingling, or weakness in hands or feet. Difficulty breathing. Tiredness. Weakness. Lower back or side pain. Clumsiness. Headache. Dizziness. Nausea. Vomiting. Cramps. Diarrhea. Drowsiness. Dry mouth. Sweating.

**Cross sensitivity:**

Persons sensitive to canrenone or canrenoate potassium may be sensitive to this material also.

**Medical conditions aggravated by exposure:**

Hyperkalemia. Anuria. Kidney impairment. Liver impairment. Diabetic nephropathy.

**POTENTIAL HEALTH EFFECTS**

**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion** May be harmful if swallowed.

**Skin** May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.

**Eyes** May cause eye irritation.

**SECTION 12: ECOLOGICAL INFORMATION**

<b>ECOTOXICITY</b>	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): 17.16* EC50: 96 Hr: Green Algae: (mg/L): 12.03*
<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: 3.56 (20 °C)
<b>MOBILITY IN SOIL</b>	Practically insoluble in water. Water Solubility 22 mg/L (25°C) Vapor Pressure 3.24E-11 mm Hg (25°C) Henry's Law Constant 1.14E-10 atm-m <sup>3</sup> /mole (25°C)
<b>OTHER ADVERSE EFFECTS</b>	Not available
<b>NOTES</b>	This product is not intended to be released into the environment *Danish QSAR database

### 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
<b>EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b>	Not listed
<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 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
SPIRONOLACTONE 52-01-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

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
SPIRONOLACTONE 52-01-7	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
SPIRONOLACTONE 52-01-7	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

Available upon request

### 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** – 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

04/2024

### SUPERSEDES

09/2023

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.