

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME MEDROXYPROGESTERONE ACETATE, USP (Micronized)

PRODUCT CODE 1422

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

RECOMMENDED USES Manufacturing and Compounding

RESTRICTIONS ON USE Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION Chronic Aquatic Toxicity (Category 2)

Toxic to Reproduction (Category 1A) Carcinogenicity (Category 1A)

Specific Target Organ Toxicity - Single Exposure (Category 3)

PICTOGRAM

SIGNAL WORD

HAZARD STATEMENT(S) Cytotoxic! Extremely hazardous to all tissues.

May cause respiratory irritation.

Toxic to aquatic life with long lasting effects. May damage fertility or the unborn child.

May cause cancer.

ADVERSE PHYSIOCHEMICAL, HUMAN **HEALTH AND ENVIRONMENTAL**

EFFECTS

Last Revision: 05/2023

Not Applicable.



PRECAUTIONARY STATEMENT(S) Prevention Wash hands thoroughly after handling.

Avoid release to the environment.

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.

Avoid breathing dust/fume/gas/mist/ vapors/spray. Use only outdoors or in a well-ventilated area.

Response IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical

advice/attention. Take off contaminated clothing and wash it before reuse.

IF EXPOSED OR CONCERNED: Get medical advice.

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison

center or doctor. Get medical help if you feel unwell.

COLLECT SPILLAGE

Storage Store locked up.

Store in a well ventilated place. Keep container tightly closed.

Disposal Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION Health Hazard 4 Flammability 0

Reactivity 0 Personal Protection K

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME Pregn-4-ene-3, 20-dione, 17-(acetyloxy)-6-methyl-, (6α)-

BOTANICAL NAME Not applicable

SYNONYM 17alpha-acetoxy-6alpha-methylprogesterone

CHEMICAL FORMULA

CHEMICAL FAMILY

CAS NUMBER

ALTERNATE CAS NUMBER

C24H34O4

T1-58-9

Not applicable

MOLECULAR WEIGHT 386.58

COMPOSITIONCHEMICAL NAMECAS NUMBEREC NUMBER% BY WEIGHTMEDROXYPROGESTERONE ACETATE71-58-9200-757-9100

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

If at any time there is skin contact with any cytotoxic drug, thoroughly wash the affected area with soap and

water for 15 minutes. The worker should not scrape or abrade the skin by using a scrub brush as this could

increase exposure. It is always recommended to seek a medical evaluation by a physician.

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

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Get emergency medical help.



SYMPTOMS CAUSED BY EXPOSURE

Refer to section 11

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM

THE CHEMICAL

FLAMMABLE PROPERTIES

HAZARDOUS COMBUSTION PRODUCTS

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Not applicable

May be combustible at high temperature

Under fire conditions, hazardous fumes will be present.

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.

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.

The use of chemical inactivates is not recommended as they may create a hazardous by-product. All contaminated areas should be cleaned a minimum of three times, and all contaminated products and equipment should be disposed of or cleaned in an appropriate manner.

CLEANUP PROCEDURE

A clearly labelled cytotoxic spill kit should be kept wherever cytotoxic medications are being prepared, stored, administered or received (shipping). A spill needs to be cleaned by members of the staff that have received the appropriate training and have the appropriate protective equipment; others should vacate the area as soon as it is safe to do so until the spill is cleaned. All spills should be immediately marked with a warning sign to prevent exposure to others. Glass should never be handled by hand; always use a scoop. The cleanup should be done by as few people as feasible, but there should be at least two people involved.

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

Cytotoxic! Extremely hazardous to all tissues. Avoid all contact. 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.

Store at 25°. Short term excursions, temperature excursions as experienced during shipping and warehousing, are permitted between 15° and 30°C.



SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: MEDROXYPROGESTERONE ACETATE CAS #: 71-58-9

	Country Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes	
		ppm	mg/m³	ppm	mg/m³				
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

Cytotoxic: There are no exposure limits set for cytotoxic drugs. Exposure must be kept to a minimum.

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Chemical splash goggles, and if necessary, full-face protection. 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: Protective gloves made of vinyl or nitrile rubber. Gloves should be changed frequently, or immediately if punctured, cut, or torn. It is also recommended that workers wear two pairs at a time for additional protection. Clothing: Wear appropriate protective clothing to minimize contact with skin. A moisture resistant, long sleeved gown with elastic cuffs. To prevent the spread of medication, protective clothing should not be worn outside of the preparation area. 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. In cases where there is a possibility of the medication becoming airborne, a powered air purifying respirator is recommended. 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.

The following engineering controls should be put in place where cytotoxic medications are being used: A minimum of a Class II biological safety cabinet with HEPA filter exhaust systems that does not allow air to be circulated back into the room should be used while manipulating cytotoxic drugs.

The preparation area within the cabinet should be covered with a plastic backed, absorbent material to reduce dispersion and facilitate the clean-up of any spilled medication.

Medications should be isolated and locked out in such a manner that only those properly trained have access to the storage location.

Puncture proof containers for the disposal of needles, syringes and vials must be provided.

Negative pressure rooms that prevent any spilled medication from leaving the room are also recommended.

BIOLOGICAL MONITORING

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CONTROL BANDING Not available

NOTES

Additional controls

Not available

Safe work procedures for handling these materials should be developed and taught to all affected staff. Proper signage informing all employees of the presence of cytotoxic drugs and their hazards must be developed and displayed in highly visible locations. Eating, drinking, smoking, applying makeup and the storage of food should

be completely prohibited in the preparation area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES



PHYSICAL STATE

Solid

DESCRIPTION

White to off-white, odorless, crystalline powder.

SOLUBILITY

Freely soluble in chloroform; soluble in acetone and in dioxane; sparingly soluble in alcohol and in methanol; slightly soluble in ether;

insoluble in water.

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

Not available

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P

(OCTANOL-WATER)

Not available LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

(200-210)°C, (392-410)°F

PARTICLE

CHARACTERISTICS

OXIDIZING PROPERTY

Not available

pН

Not available

RELATIVE DENSITY

(WATER = 1)

SPECIFIC GRAVITY

Not available

UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)

Not available

VAPOR DENSITY

(AIR = 1)

Not available

VAPOR PRESSURE

< 0.0000001 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

CHEMICAL STABILITY

INCOMPATIBLE MATERIALS

HAZARDOUS DECOMPOSITION

PRODUCTS

HAZARDOUS POLYMERIZATION

POSSIBLITY OF HAZARDOUS REACTION

CONDITIONS TO AVOID

Not established

Stable under recommended storage conditions

Alkaline metals. Peroxides.

Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

Will not occur

Not established

Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

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Oral: Rat: LD50: (mg/kg): > 6400

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.

Rabbit: Skin irritation; Result: Mild Rabbit: Skin irritation: Result: Slight.

SERIOUS EYE DAMAGE/EYE

IRRITATION

Based on available data, the classification criteria are not met.

Local effects: 100 mg Eye irritation: Result: Non-irritating.: Species: Rabbit

RESPIRATORY SENSITIZATIONDue to lack of data the classification is not possible.

SKIN SENSITIZATION 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

GERM CELL MUTAGENICITY Based on available data, the classification criteria are not met.

Exposure to cytotoxic drugs has been reported to cause increased frequency of chromosome damage in

exposed workers.

Ames test (Salmonella); Result: Negative. Chromosome aberration; Result: Positive.

Micronucleus test; Result: Negative; Species: Mouse

Sister chromatid exchange; Result: Positive.

CARCINOGENICITY OSHA MEDROXYPROGESTERONE ACETATE is not listed.

NTP MEDROXYPROGESTERONE ACETATE is not listed.

IARC MEDROXYPROGESTERONE ACETATE is listed in group 2b (possibly carcinogenic to

humans).

California This product contains the following chemical known to the State of California to cause cancer Proposition 65 and birth defects or other reproductive harm: MEDROXYPROGESTERONE ACETATE.

ADDITIONAL CARCINOGENICITY INFORMATION

REPRODUCTIVE TOXICITY

Suspected of causing cancer.

Dog: 0.2 mg/kg Carcinogenicity; Test Duration: 18 months; Result: Benign tumors. Dog: 0.3 mg/kg Carcinogenicity; Test Duration: 40 months; Result: Mammary tumors.

Repeated long-term occupational exposure to small amounts of cytotoxic drugs has not been identified to cause cancer. However, many cytotoxic drugs are known to be: Genotoxic, Carcinogenetic, Mutagenic.

The Toolbox profiler Carcinogenicity (genotox and nongenotox) alerts by ISS gives an alert for carcinogenicity; ISS Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (good reliability)

Cytotoxic drugs have also been associated with negative health effects for developing fetuses, including higher incidences of spontaneous abortions, congenital malformations, low birth weight, and infertility.

The following effects were found in human studies: effects on fertility (female fertility index), menstrual cycle changes or disorders, postpartum effects, spermatogenesis (including genetic material, sperm morphology, motility and count).

May damage fertility or the unborn child. Chromosomal abnormalities and congenital malformations, including genital abnormalities, may occur in fetuses exposed to progestins. Studies in humans have shown that medroxyprogesterone may decrease intrauterine growth.

Reproductivity

1 mg/kg/day Developmental study (intramuscular); Result: Developmental toxicity; Species: Rabbit 30 mg/kg/day Developmental study (subcutaneous); Result: Developmental abnormalities in the respiratory and urogenital systems; Species: Mouse

Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction; CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability); Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value); DART database in the Toolbox reports that this substance as Known developmental potential

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

May cause respiratory irritation.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

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Due to lack of data the classification is not possible.

MEDROXYPROGESTERONE ACETATE, USP (Micronized)



ASPIRATION HAZARDS

ROUTES OF EXPOSURE:

SIGNS AND SYMPTOMS OF EXPOSURE

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Based on available data, the classification criteria are not met

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

For progestins: Hepatitis. Porphyria. Blood clots. Jaundice. Cancer. Menstrual abnormalities.

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

For progestins: Abnormal uterine bleeding. Breast pain or tenderness. Unexpected or increased flow of breast milk. Hot flashes. Loss of sexual desires. Dry mouth. Unusual thirst. Frequent urination. Abdominal pain. Cramping. Nausea. Loss of appetite. Dizziness. Headache. Mood changes. Insomnia. Unusual tiredness or weakness. Swelling in ankles or feet. Unusual or rapid weight gain. Skin rash. Acne. Loss or gain of hair. Brown

spots on skin.

Medical conditions aggravated by exposure:

Progestins: Known or suspected cancer. Liver disease. Pregnancy. Thrombophlebitis or thromboembolic

disease.

POTENTIAL HEALTH EFFECTS Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion May be harmful if swallowed.

Skin Harmful if absorbed through skin. May cause skin irritation.

Eyes May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY EC50: 48 Hr: Crustacea: (mg/L): Not available

LC50: 96 Hr: Fish: (mg/L): 2.01*

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the

substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL Not available

MOBILITY IN SOIL Insoluble in water.

OTHER ADVERSE EFFECTS Not available

This product is not intended to be released into the environment

*Fish Acute Toxicity model (KNN/Read-Across) in VEGA (Q)SAR platform prediction (good reliability)

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment. Plastic bags that are at least 2mm thick (if polypropylene) or 4mm thick (if polyethylene) should be used to collect potentially contaminated materials. Bags should be color-coded and labelled with a cytotoxic warning label. All sharps should be placed in puncture proof containers before bagging. All workplaces should have a policy for segregating waste materials resulting from cytotoxic drug preparation and administration. These plans must meet or exceed the government regulations for hazardous waste disposal.

Housekeeping staff should wear protective gloves while handling waste containers. Cytotoxic waste must be handled differently than regular garbage and must be disposed according to government regulations. In cases where the waste is to be incinerated, it should be noted that completely sealed (airtight) containers that could build pressure and explode must be avoided. Temperatures of 1,000°C to 1,600°C should be used to render the cytotoxic drugs harmless.



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 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 Part 372.65	EPA 40 CF Appendix A	R Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
MEDROXYPROGESTERONE	N/L	N/L	N/L	N/L	N/L	N/L	X	X
ACETATE, 71-58-9								

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemcials
MEDROXYPROGESTERONE ACETATE, 71-58-9	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
MEDROXYPROGESTERONE ACETATE, 71-58-9	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

Last Revision: 05/2023

Not applicable



NOTES *Listed as the base

SECTION 16: OTHER INFORMATION

REFERENCES

DISCLAIMER

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 - 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
 05/2023

 SUPERSEDES
 05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at $\underline{www.medisca.com}$

www.medisca.com

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.

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