

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078588464

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078588498



# Material Safety Data Sheet

**I - Product Information:***Product Name:**Empirical Formula:**Chemical Name:**Uses:***Estradiol, USP** $C_{18}H_{24}O_2$ Estra-1, 3, 5(10)-triene-3, 17-diol, (17 $\beta$ )-.

Oral contraceptive; hormone replacement therapy.

**Code:** 0869, 2261**CAS#:** 50-28-2

35380-71-3 (Hemihydrate)

**II - Toxicological Information:***Irritancy:**Adverse Effect:*

May cause eye, skin, mucous membranes and respiratory tract irritation.

Toxic to the reproductive system. Repeated or prolonged exposure to the substance can produce target organ damage. May cause adverse reproductive effects and birth defects (teratogenic), cancer. May increase the risk of endometrial, uterine, and breast cancer. May cause gastrointestinal tract irritation with abdominal cramps, nausea and vomiting. May cause skin reactions, increase in blood pressure, bloating, jaundice (yellow eyes or skin), Central Nervous System effects (headache, migraine, dizziness, mental depression), steepening of corneal curvature, weight gain or loss, increase of gallbladder disease, reduced carbohydrate tolerance, change in sex drive, loss of appetite, intolerance to contact lenses, swelling due to fluid and salt retention, aggravation of porphyria. Women may develop full or tender breasts and disturbed menstrual cycle (breakthrough spotting, change in menstrual flow), increase in size of uterine fibromyomata, change in cervical erosion and amount of cervical secretion. Men may experience breast enlargement and other feminizing effects. These changes in secondary sexual characteristics are fully reversible upon cessation of exposure.

Hypersensitivity (anaphylactic) reactions may also occur.

N/A

*Toxicity Data:***III - Physical Data:***Physical State:**Description:**Solubility:**Other Physical Properties:*Liquid ☐ Solid ☒ Gas ☐

White or creamy white, small crystals or crystalline powder. Is odorless, and is stable in air. Is hygroscopic.

Practically insoluble in water; soluble in alcohol, in acetone, in dioxane, in chloroform, and in solutions of fixed alkali hydroxides; sparingly soluble in vegetable oils.

mw: 272.39 281.39(Hemihydrate) mp: 173 – 179°C (as per Merck)

**IV - Fire And Explosion Hazards:***Flammability:**Flash Point:**Extinguishing Media:**Fire-Fighting:*

May be combustible at high temperature.

N/A

Water spray, carbon dioxide, dry chemical powder alcohol pr polymer foam.

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**V - Reactivity Data:***Stability:**Incompatibilities:**Hazardous Decomp. Products:**Hazardous Polymerization:*

Stable.

Strong oxidizing agents.

Toxic fumes of carbon monoxide and carbon dioxide.

Will not polymerize.

**VI - Preventive Measures:***Personal Protective Clothing:**Preventive Measures**Specific Engineering Controls:**Spill & Leak:**Waste Disposal:**Storage:***VII - First Aid Measures:***Eyes:**Skin:**Ingestion:**Inhalation:*

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers.

Flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes.

Call a physician. Wash out mouth with water.

Remove to fresh air. If not breathing, give A.R. If breathing is difficult, give oxygen.

**NOTE:** If victim is unconscious, never induce vomiting nor give liquids. Place victim in a stable side position and keep warm.*Ecological Data:**Hazardous Ingredients:**References:*

N/A


N/A

Available on request

## SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	ESTRADIOL, USP (Hemihydrate) (Micronized)
PRODUCT CODE	0869
SUPPLIER	<p><b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</p> <p><b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</p> <p><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</p>
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Oral contraceptive; hormone replacement therapy

## SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Carcinogenicity (Category 1A) Toxic to Reproduction (Category 1B)		
PICTOGRAM			
SIGNAL WORD	Danger		
HAZARD STATEMENT(S)	May cause cancer May damage fertility or the unborn child		
AUSTRALIA-ONLY HAZARDS	Not Applicable.		
PRECAUTIONARY STATEMENT(S)	<p><b>Prevention</b> 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.</p> <p><b>Response</b> IF EXPOSED OR CONCERNED: Get medical advice/attention.</p> <p><b>Storage</b> Store locked up.</p> <p><b>Disposal</b> Dispose of contents and/or container in accordance with local regulations.</p>		
HMIS CLASSIFICATION	<p><b>Health Hazard</b> 2</p> <p><b>Reactivity</b> 0</p>	<p><b>Flammability</b> 0</p> <p><b>Personal Protection</b> G</p>	

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Estra-1, 3, 5(10)-triene-3, 17-diol, (17β)-.
BOTANICAL NAME	Not applicable

**SYNONYM** Oestradiol; Estradiol-17-beta Dihydrofollicular hormone;  $\beta$ -Estradiol hemihydrate**CHEMICAL FORMULA**  $C_{18}H_{24}O_2 \cdot \frac{1}{2}H_2O$ **CAS NUMBER** 35380-71-3 (Hemihydrate)**ALTERNATE CAS NUMBER** 50-28-2 (General)**MOLECULAR WEIGHT** 281.39

COMPOSITION		
CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
ESTRADIOL (Hemihydrate)	35380-71-3	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.

**NOTES** Chemical family: Steroid.

## 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.**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.

## 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.

### STORAGE CONDITIONS

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. Preserve in tight, light-resistant containers. Store at 25°C, excursions permitted between 15° and 30°C.

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ESTRADIOL CAS #: 35380-71-3

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

### 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.

### SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

### NOTES

USP: ELV: Industrial use: TWA: 0.1 micrograms/m<sup>3</sup>

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### PHYSICAL STATE

Solid

### DESCRIPTION

White or creamy white, small crystals or crystalline powder. Is odorless, and is hygroscopic.

### SOLUBILITY

Practically insoluble in water; soluble in alcohol, in acetone, in dioxane, and in solutions of fixed alkali hydroxides; slightly soluble in chloroform; sparingly soluble in vegetable oils.

### ODOR

Odorless

### FLAMMABILITY

May be combustible at high temperature

### ODOR THRESHOLD

Not available

pH

Not available

### MELTING POINT

(173-180)°C,  
(343.4-356)°F

<b>BOILING POINT</b>	Not available	<b>FREEZING POINT</b>	(173-180)°C, (343.4-356)°F	<b>FLASH POINT</b>	Not available
<b>SPECIFIC GRAVITY</b>	Not available	<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available
<b>UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)</b>	Not available	<b>LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)</b>	Not available	<b>VAPOR PRESSURE</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>log P (OCTANOL-WATER)</b>	3.94 (20°C)
<b>AUTO-IGNITION TEMPERATURE</b>	Not available	<b>DECOMPOSITION TEMPERATURE</b>	Not available	<b>VISCOSITY</b>	Not available

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>STABILITY</b>	Stable under recommended storage conditions
<b>MATERIALS TO AVOID</b>	Strong oxidants
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide 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>	<b>ESTRADIOL (Anhydrous):</b> Oral: Rat: LD50: (mg/kg): > 4000 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LD50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Based on available data, the classification criteria are not met. Local effects Draize irritancy test Result: Non-irritant. Species: Human Organ: Skin
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Due to lack of data the classification is not possible.
<b>RESPIRATORY OR SKIN SENSITIZATION</b>	Respiratory sensitization: Due to lack of data the classification is not possible. Skin sensitization: Based on available data, the classification criteria are not met. Sensitization test Result: Non-sensitizing. Species: Guinea pig Organ: Skin

**GERM CELL MUTAGENICITY**

Based on available data, the classification criteria are not met.  
Results for genotoxicity and mutagenicity studies were mixed.

**CARCINOGENICITY**

**OSHA** ESTRADIOL is listed.

**NTP** ESTRADIOL is listed.

**IARC** ESTRADIOL is listed in group 1 (carcinogenic to humans).

**California Proposition 65** This product contains the following chemical known to the State of California to cause cancer: ESTRADIOL.

**ADDITIONAL CARCINOGENICITY INFORMATION**

May cause cancer. In humans, long-term use of estrogens is associated with an increased risk of cancer of the endometrium, breast (male and female), and ovary. In animal studies, long-term administration of estrogens increased the incidence of cancer of the breast, cervix, vagina, uterus, testis, pancreas, and liver

**REPRODUCTIVE TOXICITY**

May damage fertility or the unborn child.

Studies suggest an association of estrogen usage with birth defects including heart defects, eye and ear abnormalities, and Down's syndrome.

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**

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

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

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

**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

For estrogens: In females and males: Nausea. Vomiting. Abdominal pain. Diarrhea. Headache. Dizziness. Drowsiness. Vision problems. Breast pain. Vaginal bleeding. Menstrual changes. Change in sex drive. Gallstones. Blood clots. Joint pain. Mood disturbances. In females: Full or tender breasts. In males: Breast enlargement.

Delayed and immediate effects of exposure

For estrogens: In females and males: Fluid retention. Jaundice. Stroke. Deep vein thrombosis. In females: Disturbed menstrual cycle. In males: Feminizing effects.

Chronic effects

Cancer.

Medical conditions aggravated by exposure

For estrogens: Abnormal genital bleeding. Breast cancer. Estrogen-dependent tumors. Endometriosis. Blood clots. Liver impairment. Kidney impairment. Porphyria. Asthma. Epilepsy. Migraine. Cardiovascular disease. Cerebrovascular disease. Hypoglycemia. Diabetes. Hypocalcemia. Systemic lupus erythematosus. High blood pressure.

**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

**Eyes** 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

IC50: 72 Hr: Algae: (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**

Not available

**BIOACCUMULATIVE POTENTIAL**

High: LogPow: 3.94 (20°C)

**MOBILITY IN SOIL**

ESTRADIOL (Anhydrous):

Water Solubility: 3.6 mg/L (27°C)

Henry's Law Constant: 3.64E-11 atm-m<sup>3</sup>/mole (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

**UNITED STATES & CANADA**
**UN PROPER SHIPPING NAME**

Not dangerous good

**UN NUMBER**

Not applicable

**CLASS**

Not applicable

**PACKING GROUP**

Not applicable

**AUSTRALIA**
**UN PROPER SHIPPING NAME**

Not dangerous good

**UN NUMBER**

Not applicable

**CLASS**

Not applicable

**PACKING GROUP**

Not applicable

**HAZCHEM**

Not applicable

**ENVIRONMENTAL HAZARDS**

Not available

**SPECIAL SHIPPING INFORMATION**

Not applicable

## SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
ESTRADIOL, 35380-71-3	N/L	N/L	N/L	N/L	X	N/L	X	X

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
ESTRADIOL, 35380-71-3	N/L	Listed as Schedule 4	N/L

## SECTION 16: OTHER INFORMATION

**REFERENCES**

Available upon request





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# SAFETY DATA SHEET

## ABBREVIATIONS AND ACRONYMS

**CAS** – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

## LAST REVISION

12/2016

## SUPERSEDES

07/2014

## 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.