


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>CLOMIPHENE CITRATE, USP</b>
<b>PRODUCT CODE</b>	<b>0390</b>
<b>SUPPLIER</b>	<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 <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 <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
<b>USES</b>	Sex hormone modulator

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Toxic to Reproduction (Category 1B) Chronic Aquatic Toxicity (Category 2)			
<b>PICTOGRAM</b>				
<b>SIGNAL WORD</b>	Danger			
<b>HAZARD STATEMENT(S)</b>	May damage fertility or the unborn child. Limited carcinogenic evidence. Toxic to aquatic life with long lasting effects.			
<b>AUSTRALIA-ONLY HAZARDS</b>	Not Applicable.			
<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>  <b>Response</b>  <b>Storage</b> <b>Disposal</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. Avoid release to the environment.  IF EXPOSED OR CONCERNED: Get medical advice/attention. COLLECT SPILLAGE.  Store locked up. Dispose of contents and/or container in accordance with local regulations.		
<b>HMS CLASSIFICATION</b>	<b>Health Hazard</b>  <b>Reactivity</b>	2  0	<b>Flammability</b>  <b>Personal Protection</b>	0  G

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

<b>CHEMICAL NAME</b>	2-[p-(2-Chloro-1,2-diphenylvinyl)phenoxy]triethylamine citrate (1:1)
<b>BOTANICAL NAME</b>	Not applicable
<b>SYNONYM</b>	Clomifene citrate; Chloramiphene citrate; Racemic clomiphene dihydrogen citrate
<b>CHEMICAL FORMULA</b>	C <sub>26</sub> H <sub>28</sub> ClNO C <sub>6</sub> H <sub>8</sub> O <sub>7</sub>
<b>CAS NUMBER</b>	50-41-9
<b>ALTERNATE CAS NUMBER</b>	Not applicable
<b>MOLECULAR WEIGHT</b>	598.0884

CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
CLOMIPHENE CITRATE	50-41-9	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.

<b>NOTES</b>	<p>Chemical family: Stilbene derivative.</p> <p>Clomiphene is a non-steroidal compound which can be separated into its Z and E isomers, zuclomifene and enclomifene. It has both oestrogenic and anti-oestrogenic properties, the latter residing mainly in the E-isomer. USP grade clomiphene citrate contains 30.0 - 50.0 % of the Z-isomer.</p>
--------------	--

## 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>SYMPTOMS AND EFFECTS</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
<b>FLAMMABLE PROPERTIES</b>	May be combustible at high temperature
<b>HAZARDOUS COMBUSTION PRODUCTS</b>	Under fire conditions, hazardous fumes will be present.
<b>EXTINGUISHING MEDIA</b>	<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.
<b>PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS</b>	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

<b>PERSONAL PRECAUTIONS</b>	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
<b>METHODS &amp; MATERIAL FOR CONTAINMENT</b>	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. 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 unlabelled 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. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours. Preserve in well-closed containers. Store at controlled room temperature. Protect from light.

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CLOMIPHENE CITRATE CAS #: 50-41-9

	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**

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE**

Solid

**DESCRIPTION**

White to pale yellow, essentially odorless powder.

<b>SOLUBILITY</b>	Slightly soluble in water and in chloroform; freely soluble in methanol; sparingly soluble in alcohol; insoluble in ether.				
<b>ODOR</b>	Essentially odorless				
<b>FLAMMABILITY</b>	May be combustible at high temperature				
<b>ODOR THRESHOLD</b>	Not available	<b>pH</b>	5 (2 %) (20°C)	<b>MELTING POINT</b>	(116-118)°C, (240.8-244.4)°F (decomposes)
<b>BOILING POINT</b>	Not available	<b>FREEZING POINT</b>	(116-118)°C, (240.8-244.4)°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>	< 0.0000001 kPa (25°C)
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>log P (OCTANOL-WATER)</b>	6.7 (20°C)
<b>AUTO-IGNITION TEMPERATURE</b>	500 °C, 932 °F	<b>DECOMPOSITION TEMPERATURE</b>	(116-118)°C, (240.8-244.4)°F	<b>VISCOSITY</b>	Not available

**NOTES** 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>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, 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): 5750 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 OR SKIN SENSITIZATION</b>	Due to lack of data the classification is not possible.

<b>GERM CELL MUTAGENICITY</b>	Due to lack of data the classification is not possible. Suspected mutagen: mutagen according to ISSSTY
<b>CARCINOGENICITY</b>	<b>OSHA</b> CLOMIPHENE CITRATE is not listed. <b>NTP</b> CLOMIPHENE CITRATE is not listed. <b>IARC</b> CLOMIPHENE CITRATE is listed in group 3 (not classifiable as to its carcinogenicity to humans). <b>California Proposition 65</b> This product contains the following chemical known to the State of California to cause cancer and birth defects or other reproductive harm: CLOMIPHENE CITRATE.
<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	One study reported an increased risk of ovarian cancer in women who had prolonged clomifene therapy (for one year or more) although not in those who received the drug for a shorter period. The conclusions of this study were limited since the numbers who developed ovarian cancer were small. A review of epidemiological and cohort studies concluded that clomifene was not associated with any increase in the risk of ovarian cancer when used for less than 12 cycles, but noted conflicting results, limitations of the data, and the need to control for infertility and nulliparity as risk factors for ovarian cancer. Further cohort and case control studies, and pooled analyses have also found no association between use of clomifene and ovarian cancer. Based on available data, the classification criteria are not met.
<b>REPRODUCTIVE TOXICITY</b>	Possible reproductive hazard. May damage fertility or the unborn child. There have been reports of birth defects and fetal death associated with clomiphene administration in humans, although a direct causal relationship has not been established. The therapeutic use of clomiphene is associated with an increased incidence of multiple births (twinning) and possible premature deliveries, as well as ectopic and heterotopic pregnancy. Clomiphene is intended to stimulate ovulation in women and increase testosterone in men. Increased fertility and adverse effects have occurred with therapeutic use. Studies in rats, mice, and rabbits have shown clomiphene to cause impaired fertility and birth defects or adverse effects in the fetus. Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction.
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	Due to lack of data the classification is not possible.
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Due to lack of data the classification is not possible.
<b>ASPIRATION HAZARDS</b>	Due to lack of data the classification is not possible.
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	Symptoms related to the physical, chemical, and toxicological characteristics: Hot flashes. Abdominal bloating or pain. Pelvic pain. Premenstrual syndrome. Weight gain. Troubled breathing. Decreased urine production. Yellow skin or eyes. Headache. Visual disturbances. Increased sensitivity of eyes to light. Tiredness. Trouble sleeping. Restlessness. Nervousness. Nausea. Vomiting. Mental depression. Breast discomfort (in women). Breast enlargement (in men). Dizziness. Increased or abnormal menstrual bleeding. Light uterine bleeding between regular menstrual periods.  Medical conditions aggravated by exposure: Ovarian cysts. Endometriosis. Mental depression. Adrenal insufficiency. Liver impairment. Abnormal genital bleeding. Uterine fibroids.
<b>POTENTIAL HEALTH EFFECTS</b>	<b>Inhalation</b> May be harmful if inhaled. May cause 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

<b>TOXICITY</b>	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 96Hr: Algae (or other aqua plants): (mg/L): <1*
<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>	Strong bioaccumulative potential: Log Pow: 6.7 (20°C)
<b>MOBILITY IN SOIL</b>	Slightly soluble in water.
<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>WASTE DISPOSAL</b>	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
-----------------------	---

## SECTION 14: TRANSPORT INFORMATION

### UNITED STATES & CANADA

<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

### AUSTRALIA

<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>HAZCHEM</b>	Not applicable

<b>ENVIRONMENTAL HAZARDS</b>	Not available
------------------------------	---------------

<b>SPECIAL SHIPPING INFORMATION</b>	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
CLOMIPHENE CITRATE 50-41-9	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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
CLOMIPHENE CITRATE 50-41-9	N/L	Listed as Schedule 4*	N/L

**NOTES**

\*Listed as the base

**SECTION 16: OTHER INFORMATION****REFERENCES**

Available upon request

**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; **HMS** – 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**

05/2018

**SUPERSEDES**

11/2015

**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.