


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>ALTRENOGEST (Not for Human Use)</b>
<b>PRODUCT CODE</b>	<b>2294</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>	Veterinary

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Toxic to Reproduction (Category 2) Toxicity - Oral (Category 5) Acute Toxicity - Dermal (Category 5) Sensitization - Skin (Category 1) Chronic Aquatic Toxicity (Category 3)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Warning
<b>HAZARD STATEMENT(S)</b>	Suspected of damaging fertility or the unborn child. May be harmful if swallowed. May be harmful if in contact with skin May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Repeated exposure may cause skin dryness or cracking.

<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>	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. Contaminated work clothing must not be allowed out of the workplace. In case of inadequate ventilation wear respiratory protection. Avoid release to the environment.		
	<b>Response</b>	IF EXPOSED OR CONCERNED: Get medical advice. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional. IF SWALLOWED: Get medical help.		
	<b>Storage</b>	Store locked up.		
	<b>Disposal</b>	Dispose of contents and/or container in accordance with local regulations.		
<b>HMS CLASSIFICATION</b>	<b>Health Hazard</b>	2	<b>Flammability</b>	0
	<b>Reactivity</b>	0	<b>Personal Protection</b>	G

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>CHEMICAL NAME</b>	(17β)-17-Hydroxy-17-(2-propenyl)-estra-4, 9, 11-trien-3-one.								
<b>BOTANICAL NAME</b>	Not applicable								
<b>SYNONYM</b>	Allyltrenbolone								
<b>CHEMICAL FORMULA</b>	C <sub>21</sub> H <sub>26</sub> O <sub>2</sub>								
<b>CHEMICAL FAMILY</b>	Not available								
<b>CAS NUMBER</b>	850-52-2								
<b>ALTERNATE CAS NUMBER</b>	Not applicable								
<b>MOLECULAR WEIGHT</b>	310.4344								
<b>COMPOSITION</b>	<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>ALTRENOGEST</td> <td>850-52-2</td> <td>212-703-1</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	ALTRENOGEST	850-52-2	212-703-1	100
CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT						
ALTRENOGEST	850-52-2	212-703-1	100						
<b>NOTES</b>	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. Synthetic Progesterone agonist								

### 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

**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: **ALTRENOGEST** CAS #: **850-52-2**

	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>				
<b>OSHA</b>	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>ACGIH</b>	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>NIOSH</b>	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>WEEL</b>	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>HSIS</b>	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>HSE</b>	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
<b>GESTIS</b>	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

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL  
STATE**

Solid

**DESCRIPTION**

White to light yellow powder or crystalline powder.

**SOLUBILITY**

Insoluble in water. Very soluble in methanol, dimethylformamide and dichloromethane.

**ODOR**

Odorless or characteristic odor

**FLAMMABILITY**

May be combustible at high temperature

<b>AUTO-IGNITION TEMPERATURE</b>	>100°C, >212°F	<b>BOILING POINT</b>	> 35°C, >95°F	<b>DECOMPOSITION TEMPERATURE</b>	>100°C, >212°F
<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	Not available
<b>log P (OCTANOL-WATER)</b>	3.710	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(115-120)°C, (239-248)°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>	Not available	<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): >2000 Dermal: Rabbit LD50: (mg/kg): >2000 Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Due to lack of data classification is not possible.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Due to lack of data classification is not possible.
<b>RESPIRATORY SENSITIZATION</b>	Based on available data, the classification criteria are not met. Similar product, Progesterone caused anaphylaxis or anaphylactoid reactions rarely.
<b>SKIN SENSITIZATION</b>	May cause allergic skin rashes. Suspected skin sensitizer: The Toolbox profiler Protein binding alerts for skin sensitization by OASIS v1.3 gives an alert for skin sensitisation.

**GERM CELL MUTAGENICITY**

Due to lack of data classification is not possible.

**CARCINOGENICITY**

**OSHA** ALTRENOGEST is not listed.

**NTP** ALTRENOGEST is not listed.

**IARC** ALTRENOGEST is not evaluated.

**California Proposition** 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.

In a cohort study of women aged 40 to 64 years, the premenopausal use of oral progestogens alone, mainly for benign breast, uterine, and ovarian conditions, and irregular menstruation, was not associated with an increased risk of breast cancer. However, the data did suggest that there was an increased risk of current users of progestogens for longer than 4.5 years compared to women who had never used progestogens. Limitations of this study included the lack of analysis of different progestogens or a record of the reasons for progestogen treatment.

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

**REPRODUCTIVE TOXICITY**

Suspected of damaging fertility of unborn child.

Some progestogens when given during pregnancy have been reported to cause virilisation (masculinization) of a female fetus. This appears to have been associated with those progestogens with more pronounced androgenic activity such as norethisterone; the natural progestogenic hormone progesterone and its derivatives such as dydrogesterone and medroxyprogesterone do not appear to have been associated with such effects.

A large study compared a contraceptive progesterone-releasing vaginal ring and a copper IUD for 1 year in breast-feeding women. There was little difference in infant weight gain during the study, although at 12 months the infants of mothers using IUD were breast-fed less frequently, receiving more supplementary feeding, and were heavier. There was no effect of progesterone on lactation or infant growth. Further smaller studies have also found no adverse effect on lactation or infant growth. The American Academy of Pediatrics has found no reports of adverse effects in breast-fed infants of mothers given progesterone, and therefore considers it to be usually compatible with breast feeding.

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)

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**

Due to lack of data classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

Due to lack of data classification is not possible.

**ASPIRATION HAZARDS**

Due to lack of data classification is not possible.

**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

May cause gastrointestinal disturbances, changes in appetite or weight, fluid retention, oedema, acne, chloasma, (melasma), allergic skin rashes, urticaria, mental depression, breast changes including discomfort or occasionally gynaecomastia, changes in libido, hair loss, hirsutism, fatigue, drowsiness or insomnia, fever, headache, premenstrual syndrome-like symptoms, and altered menstrual cycles or irregular menstrual bleeding.

Anaphylaxis or anaphylactoid reactions may occur, and rarely alterations in liver-function tests and jaundice.

<b>POTENTIAL HEALTH EFFECTS</b>	<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation. Anaphylaxis or anaphylactoid reactions may occur.
	<b>Ingestion</b>	May be harmful if swallowed.
	<b>Skin</b>	May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.
	<b>Eyes</b>	May cause eye irritation.

## SECTION 12: ECOLOGICAL INFORMATION

<b>ECOTOXICITY</b>	EC50: 48 Hr: Crustacea: Daphnia (mg/L): 3.12* LC50: 96 Hr: Fish: (mg/L): 0.3884* - 13.05 EC50: 96 Hr: Algae: Green Algae: (mg/L): 3.28**
<b>PERSISTENCE AND DEGRADABILITY</b>	Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q SAR platform predicts that the chemical is NON Readily Biodegradable (moderate reliability). The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.
<b>BIOACCUMULATIVE POTENTIAL</b>	Log Pow: 3.710 BCF: 130.7
<b>MOBILITY IN SOIL</b>	Insoluble 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 (moderate reliability) **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

**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	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
ALTRENOGEST 850-52-2	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	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
ALTRENOGEST 850-52-2	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
ALTRENOGEST 850-52-2	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**

02/2023

**SUPERSEDES**

04/2021

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.