



# HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.  
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250  
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

## SAFETY DATA SHEET

Section 1: Identification	
<b>Section 1, Identification</b>	
<b>GHS Product identifier</b>	Drospirenone and Ethinyl Estradiol Tablets USP 3 mg/0.03 mg
<b>Trade Name</b>	Not applicable
<b>Other means of identification Synonyms</b>	Drospirenone and Ethinyl Estradiol, Finished product
<b>Recommended use</b>	Pharmaceutical product to prevent pregnancy
<b>Manufacturer</b>	Cyndea
<b>Distributor</b>	Camber Consumer care, Inc., Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Fire and Explosion</b>	Expected to be non-combustible
<b>Health</b>	<p>Do not prescribe Drospirenone and Ethinyl Estradiol Tablets USP to women who are known to have the following:</p> <ul style="list-style-type: none"><li>• Renal impairment</li><li>• Adrenal insufficiency</li><li>• A high risk of arterial or venous thrombotic diseases.</li></ul> <p>Examples include women who are known to:</p> <ul style="list-style-type: none"><li>• Smoke, if over age 35</li><li>• Have deep vein thrombosis or pulmonary embolism, now or in the past</li><li>• Have cerebrovascular disease</li><li>• Have coronary artery disease</li><li>• Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)</li><li>• Have inherited or acquired hypercoagulopathies</li><li>• Have uncontrolled hypertension</li><li>• Have diabetes mellitus with vascular disease</li></ul>



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	<ul style="list-style-type: none"><li>• Have headaches with focal neurological symptoms or have migraine headaches with or without aura if over age 35</li><li>• Undiagnosed abnormal uterine bleeding</li><li>• Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past</li><li>• Liver tumors, benign or malignant, or liver disease</li><li>• Pregnancy, because there is no reason to use COCs during pregnancy</li></ul>
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Ingredients</b> Drospirenone USP Ethinyl Estradiol USP	<b>CAS</b> 67392-87-4 57-63-6
<b>Section 4: First-Aid Measures</b>	
<b>Inhalation</b>	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
<b>Skin Contact</b>	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
<b>Eye Contact</b>	Flush eyes with plenty of water. Get medical attention.
<b>Ingestion</b>	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention
<b>NOTES TO HEALTH PROFESSIONALS</b>	



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<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
<b>OVERDOSAGE</b>	There have been no reports of serious ill effects from overdose, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea. DRSP is a spironolactone analogue which has anti-mineralocorticoid properties. Serum concentration of potassium and sodium, and evidence of metabolic acidosis, should be monitored in cases of Overdose.
<b>Section 5: Fire-Fighting Measures</b>	
<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
<b>Section 6: Accidental Release Measures</b>	
<b>Personal precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.



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<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal.
<b>Section 7: Handling and Storage</b>	
<b>Handling</b>	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
<b>Storage</b>	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [See USP Controlled Room Temperature].
<b>Section 8: Exposure Controls/Personal Protection</b>	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.	
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical Form</b>	<b>How Supplied</b> Drospirenone and Ethinyl Estradiol Tablets, USP are available in package of one blister pack (NDC 31722-945-32) and three blister packs (NDC 31722-945-31) Each blister pack contains 28 film-coated tablets in the following order: <ul style="list-style-type: none"><li>• 21 yellow, round, biconvex, film-coated tablets marked with a "30" on one side each containing 3 mg drospirenone (DRSP) and 0.03 mg ethinyl estradiol (EE).</li><li>• 7 white, round, biconvex, film-coated tablets marked with "PL" on one side.</li></ul>
<b>Section 10: Stability and Reactivity</b>	
Stable under recommended storage conditions.	
<b>Section 11: Toxicological Information</b>	
<b>Carcinogenesis, Mutagenesis, Impairment of Fertility</b>	In a 24 month oral carcinogenicity study in mice dosed with 10 mg/kg/day DRSP alone or 1 + 0.01, 3 + 0.03 and 10 + 0.1 mg/kg/day of DRSP and EE, 0.1 to 2 times the exposure (AUC of DRSP) of women taking a contraceptive dose, there was an increase in carcinomas of the harderian gland in the group that received the high dose of DRSP alone. In a similar study in rats given 10 mg/kg/day DRSP alone or 0.3 + 0.003, 3 + 0.03 and 10 + 0.1 mg/kg/day DRSP and EE, 0.8 to 10 times the exposure of women taking a contraceptive dose, there was an increased incidence of benign and total (benign and malignant) adrenal gland pheochromocytomas in the group receiving the high dose of DRSP. Mutagenesis studies for DRSP were conducted <i>in vivo</i> and <i>in vitro</i> and no evidence of mutagenic activity was observed.



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## Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

## Section 14: Transport Information

### IATA/ICAO - Not Regulated

IATA Proper shipping Name	: N/A
IATA UN/ID No	: N/A
IATA Hazard Class	: N/A
IATA Packaging Group	: N/A
IATA Label	: N/A

### IMDG - Not Regulated

IMDG Proper shipping Name	: N/A
IMDG UN/ID No	: N/A
IMDG Hazard Class	: N/A
IMDG Flash Point	: N/A
IMDG Label	: N/A

### DOT - Not Regulated

DOT Proper shipping Name	: N/A
DOT UN/ID No	: N/A
DOT Hazard Class	: N/A
DOT Flash Point	: N/A
DOT Packing Group	: N/A
DOT Label	: N/A

## Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

## Section 16: Other Information

### Section 16, Other information

**Issue Date : 30-09-2020**

**Version : 00**

### Further information

**Revision note: New issue**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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