



## **SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Material</b>	Levonorgestrel and Ethinyl Estradiol tablets 0.1 mg/0.02 mg
<b>Recommended use</b>	Pharmaceutical product used as oral contraceptive
<b>Manufacturer</b>	Cyndea
<b>Distributor</b>	Camber Consumer care, Inc., Piscataway, NJ 08854
<b>Section 2: Hazard(s) Identification</b>	
<b>Statement of Hazard</b>	May damage fertility or the unborn child.
<b>Additional Hazard Information</b>	Dust may be absorbed through the skin and cause systemic effects. May be harmful if swallowed. (based on components). Accidental ingestion may cause effects similar to those seen in clinical use.  Occupational exposure to components of this mixture has resulted in menstrual irregularities in women and breast changes (enlargement, mammary secretions), loss of libido, and changes in sex hormone levels in men.
<b>Known Clinical Effects</b>	The use of oral contraceptives is associated with increased risks of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease. The most common adverse effects seen during clinical use of oral contraceptives are menstrual irregularities.
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Ingredients</b>	<b>CAS</b>
Levonorgestrel	797-63-7
Ethinyl Estradiol	57-63-6
Lactose monohydrate	10039-26-6
Microcrystalline cellulose	9004-34-6
Croscarmellose sodium	74811-65-7
Povidone	25655-41-8
Acetone	67-64-1
Colloidal silicon dioxide	112926-00-8
Magnesium stearate	557-04-0



<b>Section 4: First-Aid Measures</b>	
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Section 5: Fire-Fighting Measures</b>	
<b>Extinguishing Media</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Special Firefighting Procedures</b>	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Section 6: Accidental Release Measures</b>	
<b>Clean-up Methods</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Health and Safety Precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Environmental Protections</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
<b>Section 7: Handling and Storage</b>	
<b>General Handling</b>	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, Restrict access to work area. avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Storage:</b>	Store as directed by product packaging
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Engineering Controls</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne



	contamination levels below the exposure limits listed above in this section
<b>Environmental Exposure Controls</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical Form</b>	Tablet
<b>Colour</b>	Active Tablet: White Placebo Tablet: Orange
<b>Description</b>	<p><b>Levonorgestrel and Ethinyl Estradiol Tablets USP 0.1 mg/0.02 mg</b> are available in package of blister of 3x28 tablets, NDC 31722-936-32, as follows:</p> <p>21 active tablets: white, round biconvex tablets marked with “LE ” on one side.</p> <p>7 inert tablets: orange, round biconvex tablets marked with “PL” on one side.</p> <p><b>Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]</b></p>
<b>Section 10: Stability and Reactivity</b>	
<b>Chemical Stability</b>	: Stable under normal conditions of use.
<b>Conditions to Avoid</b>	: Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials</b>	: As a precautionary measure, keep away from strong oxidizers.
<b>Section 11: Toxicological Information</b>	
<b>General Information:</b>	
The information included in this section describes the potential hazards of the individual ingredients.	
<b>Acute Toxicity: (Species, Route, End Point, Dose)</b>	
Levonorgestrel:	
Rat	Oral LD50 > 4000 mg/kg
Mouse	Oral LD50 > 4000 mg/kg
Ethinyl Estradiol	
Mouse	Oral LD50 1737 mg/kg
Rat	Oral LD50 1200 mg/kg
<b>Section 12: Ecological Information</b>	
<b>Environmental Overview:</b>	
The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.	



### Section 13: Disposal Considerations

**Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### Section 14: Transport Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### Section 15: Regulatory Information

**EU Indication of danger:**

Carcinogenic: Category 1

Toxic to reproduction: Category 1

**EU Safety Phrases:**

S36/37 - Wear suitable protective clothing and gloves.

S22 - Do not breathe dust.

S53 - Avoid exposure - obtain special instructions before use.

S57 - Use appropriate containment to avoid environmental contamination.

### Section 16: Other Information

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**Further information**

**Revision date: New issue**

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