

# MATERIAL SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

<b>Material</b>	<b>Levonorgestrel and Ethinyl Estradiol Tablets USP (0.1 mg/0.02 mg) and Ethinyl Estradiol Tablets USP (0.01 mg)</b>
<b>Manufacturer</b>	Lupin Limited Pithampur (M.P.) - 454 775 INDIA
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. Harborplace Tower, 21 <sup>st</sup> Floor 111, South Calvert Street Baltimore, MD 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

## 2. COMPOSITION / INFORMATION ON INGREDIENTS

<b>Ingredients</b>	<b>CAS</b>
Levonorgestrel	797-63-7
Ethinyl Estradiol	57-63- 6

## 3. HAZARD IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible
<b>Health</b>	<p>Do not prescribe levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets to women who are known to have the following conditions:</p> <ol style="list-style-type: none"><li>1. A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:<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></ul></li></ol>

- Have hypercoagulopathies
  - Have uncontrolled hypertension
  - Have diabetes with vascular disease
  - Have headaches with focal neurological symptoms or have migraine headaches with or without aura if over age 35
2. Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past
  3. Liver tumors, benign or malignant, or liver disease
  4. Pregnancy, because there is no reason to use OCs during pregnancy

**Environment**

No information is available about the potential of this product to produce adverse environmental effects.

**4. FIRST AID MEASURE**

**Ingestion**

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.

**Inhalation**

Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.

**Skin Contact**

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.

**Eye Contact**

Flush eyes with plenty of water. Get medical attention.

**NOTES TO HEALTH PROFESSIONALS**

**Medical Treatment**

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.

**OVERDOSAGE**

There have been no reports of serious ill effects from overdose, including ingestion by children.

Overdosage may cause withdrawal bleeding in females and nausea.

## 5. FIRE FIGHTING MEASURE

<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.

## 6. ACCIDENTAL RELEASE MEASURES

<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.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal.

## 7. HANDLING AND STORAGE

<b>Handling</b>	No special control measures required for the normal handling of this product.
<b>Storage</b>	Store at 25° C (77° F); excursions permitted to 15°- 30° C (59°- 86° F) [see USP Controlled Room Temperature]

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Physical Form

Levonorgestrel and Ethinyl Estradiol Tablets USP (0.1 mg/0.02 mg) and Ethinyl Estradiol Tablets USP (0.01 mg) are available in Extended-Cycle Wallets, that contains 84 orange tablets each containing 0.1 mg levonorgestrel and 0.02 mg ethinyl estradiol and 7 mustard tablets each containing 0.01 mg of ethinyl estradiol. Orange tablets are round biconvex film-coated tablets, debossed with "LU" on one side and "T41" on the other side. Mustard tablets are round biconvex film-coated tablets debossed with "LU" on one side and "V22" on the other side.

They are supplied as follows:

Levonorgestrel and Ethinyl Estradiol Tablets USP (0.1 mg/0.02 mg) and Ethinyl Estradiol Tablets USP (0.01 mg) are available in an extended cycle wallet of 91 tablets which is packed in a pouch (NDC 68180-848-11).

Such two pouches are packed in a carton (NDC 68180-848-13).

## 10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## 11. TOXICOLOGICAL INFORMATION

### Carcinogenesis, Mutagenesis, Impairment of Fertility

Women who currently have or have had breast cancer should not use COCs because breast cancer may be hormonally sensitive. There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings. Some studies suggest that COCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings are due to differences in sexual behavior and other factors.

Discontinue COCs if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function. Hepatic adenomas are associated with COC use. An estimate of the attributable risk is 3.3cases/100,000 COC users. Rupture of hepatic adenomas may cause death through intraabdominal hemorrhage. Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (> 8 years) COC users. However, the attributable risk of liver cancers in COC users is less than onecase per million users.Oral contraceptive-related cholestasis may occur in women with a history of pregnancy-related cholestasis.

Women with a history of COC-related cholestasis may have the condition recur with subsequent COC use.

## 12. ECOLOGICAL INFORMATION

No relevant studies identified.

## 13. DISPOSAL CONSIDERATION

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

## 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

## 15. REGULATORY INFORMATION

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

## 16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

**Lupin** shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.