

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Enskyce™ Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/0.03 mg
Identified uses of the substance or mixture	Pharmaceutical
Manufacturer	Lupin Limited Pithampur (M.P.) – 454 775 INDIA.
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Classification of the substance or mixture

Carcinogenicity, Category 1A	H350: May cause cancer
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

Label elements

Hazard pictograms



Signal word

Danger

Hazard statements

H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P201 Obtain special instructions before use.
 P260 Do not breathe dust.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage

Hazardous components which must be listed on the label:

Desogestrel
 Ethinylestradiol

Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling, or other means.

Section 3: Composition/Information on Ingredients

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Ingredients	CAS No.	Ingredients	CAS No.
Desogestrel USP	54024-22-5	Col. Silicon Dioxide NF/EP	7631-86-9
Ethinyl Estradiol USP	57-63-6	Talc USP	14807-96-6
Lactose Monohyd NF/EP	10039-26-6	Magnesium Stearate	557-04-0
Vitamin E USP	10191-41-0	Starch NF/EP	9005-25-8
Povidone (K 30) USP/EP	9003-39-08	Stearic Acid NF 50	57-11-4
Methyl Alcohol NF	67-56-1	Purified Water USP	7732-18-5

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

General advice

In the case of accident or if you feel unwell, seek medical advice immediately.

Protection of first aiders

When symptoms persist or in all cases of doubt seek medical advice. First Aid responders should pay attention to self-protection and use the recommended personal protective equipment when the potential for exposure exists.

Inhaled

If inhaled, remove to fresh air. Get medical attention.

Skin contact

In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eye contact

If in eyes, rinse well with water. Get medical attention if irritation develops and persists

If swallowed

If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Section 5: Fire-Fighting Measures

Specific hazards during firefighting	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Clean-up Methods	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases.

Section 7: Handling and Storage

Handling	Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Section 9: Physical and Chemical Properties

Physical Form

Enskyce Tablets are available in a blister (NDC 68180-739-71) containing 28 tablets packed in a pouch (NDC 68180-739-71). Such three pouches are packaged in a carton (NDC 68180-739-73).

Each blister contains 28 film-coated tablets in the following order:

- Each of the 21-light orange, round, biconvex, film-coated tablet contains 0.15 mg of desogestrel and 0.03 mg of ethinyl estradiol USP and is debossed with "L" on one side and "J7" on the other side.
- Each of the 7 green, mottled, round, biconvex tablet debossed with "LU" on one side and "L22" on the other side.

Odour	No data available
pH	No data available
Melting point/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability (liquids)	No data available
Upper explosion limit / Upper flammability limit	No data available
Lower explosion limit / Lower flammability limit	No data available
Vapour pressure	No data available
Relative vapour density	No data available
Relative density	No data available
Solubility(ies) Water solubility	No data available
partition coefficient: n octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity Viscosity, kinematic	No data available
Explosive properties	No data available
Not explosive	No data available

Section 10: Stability and Reactivity

Stability	Stable under normal conditions.
Reactivity	Not classified as a reactivity hazard.
Hazardous reactions	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	Heat, flames and sparks. Avoid dust formation.
Hazardous decomposition products	No hazardous decomposition products are known.

Section 11: Toxicological Information

Details	Desogestrel	Ethinyl Estradiol
Information on likely route of exposure	Oral	Oral
Inhalation	No adverse effects due to inhalation are expected.	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation.
Skin Contact	Prolonged skin contact may cause temporary irritation.	Prolonged skin contact may cause temporary irritation.
Ingestion	Vomiting, diarrhea, water retention, sodium retention, gastrointestinal discomfort, mental depression, amenorrhea, insomnia, impaired glucose tolerance, pulmonary embolism Target Organs: Uterus (including cervix), Mammary gland.	Nausea and vomiting, undesirable uterine growth, proliferation and withdrawal bleeding or loss of periods. It causes enlargement of the breasts in males. Other side effects include weight gain, swelling, breast tenderness, liver dysfunction, jaundice, depression, headache, and dizziness. Growth may be stunted due to premature closing of the growth plates. Skin reactions can include excess pigmentation of the face, rashes, and hives. Redness, itching and blistering has also been reported.
Eye Contact	Direct contact with eyes may cause temporary irritation.	Direct contact with eyes may cause temporary irritation.
Acute Toxicity	LD ₅₀ (Rat oral, male and female): > 2,000 mg/kg. LD ₅₀ (Mouse oral, male and female): > 2,000 mg/kg.	Mouse- Oral LD ₅₀ 1737 mg/kg. Rat - Oral LD ₅₀ 1200 mg/kg.
Respiratory/ Skin Sensitization	No sensitizing effects known.	No sensitizing effects known.
Mutagenicity	Negative Bacterial reverse mutation assay (Ames) and Micronucleus test.	<ul style="list-style-type: none"> • Negative in Bacterial Mutagenicity (Ames) Salmonella. • Positive in Chromosome Aberration Human Lymphocytes. • Positive in Sister Chromatid Exchange Human Lymphocytes. • Positive Chromosome Aberration Chinese Hamster Ovary (CHO) cells. Positive in Vivo Micronucleus Mouse Bone Marrow
Carcinogenicity	Suspected of causing cancer.	Suspected of causing cancer.
Reproduction toxicity	May damage fertility. Suspected of damaging the unborn child.	Laboratory experiments have shown teratogenic effects. Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.
Cytotoxicity	Not Available	Cytotoxicity in isolated rat hepatocytes.

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

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 SDS.