LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	**Minzoya™ Tablets**
Identified uses of the substance or mixture	Pharmaceutical
Manufacturer	**Lupin Limited** Pithampur (M.P.) – 454 775 INDIA.
Distributor	Lupin Pharmaceuticals, Inc. Naples FL, 34108 United States

Section 2: Hazard(s) Identification

Health	Not suspected of being a human carcinogen. Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Environment	None Identified.
Precautionary statements	IF ON SKIN: Wash with plenty of soap and water If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. Do not handle until all safety precautions have been read and understood. Store locked up. Dispose of contents/ container to an approved waste disposal plant Wear protective gloves/protective clothing/eye protection/face protection. Avoid contact during pregnancy/while nursing Wash face, hands and any exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product.
Other hazards	No data available.

Section 3: Composition/Information on Ingredients

Levonorgestrel And Ethinyl Estradiol Tablets USP 0.1mg/0.02mg

Ingredients	CAS No.	Ingredients	CAS No.
Levonorgestrel USP	797-63-7	Povidone USP	9003-39-8
Ethinyl Estradiol USP	57-63-6	Methylene Chloride NF	75-09-2
Lactose Monohydrate NF	63-42-3	Croscarmellose Sodium NF	9004-32-4
Microcrystalline Cellulose NF	9004-34-6	Magnesium Stearate NF	557-04-0

Ferrous Bisglycinate Tablets 36.5 Mg

Ingredients	CAS No.	Ingredients	CAS No.
Ferrous Bisglycinate	20150-34-9	Maltodextrin	9050-36-6
Microcrystalline Cellulose	9004-34-6	Colloidal Silicon Dioxide	60676-86-0
Povidone	003-39-8	Isopropyl alcohol	67-63-0
Croscarmellose Sodium	9004-32-4	Crospovidone	9003-39-8
Magnesium Stearate	557-04-0	Opadry Blue	13463-67-7

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

Section 4: First-Aid Measures

General advice — Immediate medical attention is required.

Protection of first aiders — First Aid responders should pay attention to self-protection and use the recommended personal protective equipment when the potential for exposure exists.

Inhaled — If dust is inhaled, remove from contaminated area. Encourage patient to blow nose to ensure clear passage of breathing. If irritation or discomfort persists, seek medical attention.

Skin contact — Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

Eye contact — Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

If swallowed — If swallowed do not induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice.

Section 5: Fire-Fighting Measures

Specific hazards during firefighting — Exposure to combustion products may be a hazard to health.

Extinguishing Media — Small Fires - Foam. Dry chemical powder. BCF (where regulations permit). Carbon dioxide. Large fires - Water spray or fog.

Special Firefighting Procedures — Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Hazardous Combustion Products — Combustion products include - carbon monoxide (CO, carbon dioxide (CO2), nitrogen oxides (NOx), metal oxides, other pyrolysis products typical of burning organic material.

Section 6: Accidental Release Measures

Personal Precautions	No special controls or personal protection required under conditions of intended use. Use personal protective equipment. Ensure adequate ventilation. Refer to Section 8.
Environmental Precautions	Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.
Clean-up Methods	Sweep up and shovel into suitable labelled container containers for disposal.

Section 7: Handling and Storage

Handling	Limit all unnecessary personal contact. Use personal protective equipment as required.
Storage	Keep tightly closed. Store at room temperature between 20°C to 25°C. Protect from light. Keep out of the reach of children.

Section 8: Exposure Controls/Personal Protection

Engineering Measures/Controls:	General exhaust is adequate under normal operating conditions. The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Good general ventilation should be used.
Personal Protective Equipment:	Respiratory: Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations. Eye/Face: No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered. Skin/Body: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product.

Section 9: Physical and Chemical Properties

HOW SUPPLIED	Minzoya is available in a blister pack containing 28 tablets arranged in 3 rows of 7 active tablets and 1 row of inactive tablets, as follows: 21 Active tablets: White to off-white round biconvex tablets, debossed with “J3” on one side and plain on other side; and each containing levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg. 7 Inactive tablets: Blue colored round biconvex film coated tablets, debossed with “J4” on one side and plain on the other side containing ferrous bisglycinate 36.5 mg.

	Minzoya is available in the following configurations: Carton of one 1-cycle blister pack (NDC 70748-322-12) Carton of two 1-cycle blister packs (NDC 70748-322-13) Carton of three 1-cycle blister packs (NDC 70748-322-14)
Odor	No information available
pH	No information available
Melting point/freezing point	No information available
Initial boiling point and boiling range	No information available
Flash points	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability (liquids)	No information available
Upper explosion limit / Upper Flammability limit	No information available
Lower explosion limit / Lower flammability limit	No information available
Vapor pressure	No information available
Relative vapor density	No information available
Relative density	No information available
Solubility & Water solubility	No information available
Partition coefficient	No information available
Auto-ignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available
Explosive properties	No information available

Section 10: Stability and Reactivity

Stability	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
Reactivity	Avoid reaction with oxidizing agents
Hazardous reactions	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
Conditions to avoid	Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result
Hazardous decomposition products	Combustion products include - carbon monoxide (CO, carbon dioxide (CO2), nitrogen oxides (NOx), metal oxides, other pyrolysis products typical of burning organic material.

Section 11: Toxicological Information

Inhalation	Not normally a hazard due to physical form of product.
Skin Contact	Not normally a hazard due to physical form of product.

Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. The estrogens may produce dose-related nausea and vomiting, undesirable uterine growth, proliferation and withdrawal bleeding or loss of periods. It causes enlargement of the breasts in males.
Eye Contact	Not normally a hazard due to physical form of product.
Carcinogenicity	Ethinyl Estradiol - Substance anticipated to be Carcinogen. Levonorgestrel - Possibly Carcinogenic to Humans. (This substance has been classified by the IARC as Group 2B). Carcinogenic to Humans (This substance has been classified by the IARC as Group 1)
Reproduction toxicity	Animal testing suggests that estradiol can cause an increased risk of benign and malignant tumors of the female reproductive system and other organs.

Section 12: Ecological Information

Eco toxicity	None Identified
Reactivity	Avoid reaction with oxidizing agents
Hazardous reactions	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
Conditions to avoid	Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result
Hazardous decomposition products	Combustion products include - carbon monoxide (CO, carbon dioxide (CO2), nitrogen oxides (NOx), metal oxides, other pyrolysis products typical of burning organic material.

Section 13: Disposal Considerations

Dispose of contents/containers in accordance with local 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.