

LUPIN LIMITED

Safety Data Sheet

Section 1: Identification

Material : **My Way®**
(levonorgestrel) Tablet, 1.5 mg

Manufacturer : Lupin Limited
Pithampur (M.P.) - 454 775
INDIA.

Distributor : Lupin Pharmaceuticals, Inc.
Harborplace Tower, 21st Floor
111, South Calvert Street
Baltimore, MD 21202
United States
Tel. 001-410-576-2000
Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Fire and Explosion : Expected to be non-combustible

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

Section 3: Composition/Information on Ingredients

Ingredients : **CAS**

Levonorgestrel USP : 797-63-7

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Section 4: First-Aid Measures

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.
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.

Section 5: Fire-Fighting Measures

Fire and Explosion Hazards	:	Assume that this product is capable of sustaining combustion.
Extinguishing Media	:	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	:	For single units (packages): No special requirements needed. 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.
Hazardous Combustion Products	:	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

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Section 6: Accidental Release Measures

- Personal Precautions** : Wear protective clothing and equipment consistent with the degree of hazard.
- Environmental Precautions** : For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
- Clean-up Methods** : Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage

- Handling** : No special control measures required for the normal handling of 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

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

Section 9: Physical and Chemical Properties

- Physical Form** : The My Way® (levonorgestrel) Tablet, 1.5 mg is available in following packaging configurations:
1. A blister containing 1 tablet. Each blister is packed in a carton (NDC 68180-852-11).
 2. A blister containing 1 tablet. Each blister is packed in a carton (NDC 68180-852-12). Two such cartons are packed in Sleeve.
- The tablet is white to off white, round biconvex shaped, debossed with "LU" on one side and "S25" on the other side.

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

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Section 11: Toxicological Information

Not Reported

Section 12: Ecological Information* (non-mandatory)

No relevant studies identified.

Section 13: Disposal Considerations* (non-mandatory)

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

Section 14: Transport Information* (non-mandatory)

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

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Section 15: Regulatory Information* (non-mandatory)

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 MSDS.