

LUPIN PHARMACEUTICALS, INC.

SAFETY DATA SHEET

Section 1: Identification

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| Material | Merzee (Norethindrone Acetate and Ethinyl Estradiol Capsules, 1 mg/20 mcg, and Ferrous Fumarate Capsules) |
| Manufactured by | SLAYBACK PHARMA LLC 301 Carnegie Center, Suite 303 Princeton, NJ 08540 Tel: +1-844 566 2505 Fax: 609 455 1514 |
| Manufactured for | 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 |
| Recommended use of the chemical and restrictions on use | Pharmaceuticals |

Section 2: Hazard(s) Identification

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| Classification of the substance or mixture | Drugs in the finished state and intended for the final user are not subject to labelling in the US, EU, or Canada. Please consult the prescribing/packaging information. The classification and labelling listed below is for bulk drug product |
| Carcinogenicity | Category 1A |
| Germ cell mutagenicity | Category 2 |
| Reproductive toxicity | Category 1B |
| Effects on or via lactation | Yes |
| Specific target organ toxicity – (repeated exposure) | Category 2 |
| Label elements | |
| Signal Word | Danger |
| |  |
| Hazard Statements | H341 - Suspected of causing genetic defects H350 - May cause cancer H360 - May damage fertility or the unborn child H362 - May cause harm to breast-fed children H373 - May cause damage to organs through prolonged or repeated exposure |
| Precautionary Statements | Do not handle until all safety precautions have been read and understood P281 - Use personal protective equipment as required |

P405 - Store locked up
 P280 - Wear protective gloves/protective clothing/eye protection/face protection
 P201 - Obtain special instructions before use
 P263 - Avoid contact during pregnancy/while nursing
 P264 - Wash face, hands and any exposed skin thoroughly after handling
 P270 - Do not eat, drink or smoke when using this product
 P308 + P313 - IF exposed or concerned: Get medical advice/attention
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray
 P314 - Get medical advice/attention if you feel unwell
 P501 - Dispose of contents/ container to an approved waste disposal plant

Section 3: Composition/Information on Ingredients

Substance / Mixture Mixture

Hazardous Components

| Chemical name | CAS-No. | Concentration (% w/w)* |
|-----------------------|-----------|------------------------|
| Sesame Oil | 8008-74-0 | 10-30 |
| Gelatin Type A NF | 9000-70-8 | 10-30 |
| Ferrous fumarate | 141-01-5 | 10-30 |
| Norethindrone acetate | 51-98-9 | 10-30 |
| Ethynyl estradiol | 57-63-6 | 1-5 |

* The exact percentage (concentration) of composition has been withheld as a trade secret

Section 4: First-Aid Measures

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| Eye Contact: | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical attention immediately. |
| Skin Contact: | Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention. |
| Ingestion | 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. |
| Inhalation: | Remove to fresh air and keep patient at rest. Seek medical attention immediately. |
| Most Important Symptoms and Effects of Exposure/acute and delayed | There have been no reports of serious ill effects from overdose of oral contraceptives, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea. The most common adverse reactions in clinical trials ($\geq 2\%$) are headache, vaginal candidiasis, nausea, menstrual cramps, breast tenderness, bacterial vaginitis, abnormal cervical smear, acne, mood swings, and weight gain. |
| Indication of immediate medical attention and special treatment needed: | No data |

Section 5: Fire-Fighting Measures

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| Extinguishing Media | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Unsuitable extinguishing media | Not known |

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| Specific hazards arising from the chemical | Fire may produce irritating, corrosive and/or toxic gases |
| Special protective equipment and precautions for firefighters | Wear suitable protective equipment |
| Fire-fighting equipment/instructions | Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. |

Section 6: Accidental Release Measures

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| Personal Precautions, Protective Equipment, and Emergency Procedures | Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. |
| Environmental Precautions | Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release. See Section 12 for additional ecological information. |
| Methods and Material for Containment and Cleaning Up | |
| Measures for Cleaning /Collecting | Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly |
| Additional Consideration for Large Spills: | Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel |

Section 7: Handling and Storage

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| Precautions for Safe Handling | Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Releases to the environment should be avoided. 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 or other equivalent controls. |
| Conditions for Safe Storage, Including any Incompatibilities: | |
| Storage Conditions | Store as directed by product packaging. Keep out of reach of children |
| Specific end use(s) | Pharmaceutical drug substance |

Section 8: Exposure Controls/Personal Protection

Biological limit values (occupational exposure limits):

| Compound | Issuer | Type | OEL (µg/m³) |
|-----------------------|----------|------|-------------|
| Ferrous fumarate | Allergan | TWA | 1000 |
| Norethindrone acetate | Allergan | TWA | 0.50 |

| | | | |
|-------------------|----------|-----|------|
| Ethynyl estradiol | Allergan | TWA | 0.01 |
|-------------------|----------|-----|------|

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|---------------------------------------|---|
| Exposure/Engineering Controls | None required for normal handling of filled capsules and packaged product. If capsules are crushed or broken: Control exposures to below the OEL containment devices and personal protective equipment should be used while handling the powder . Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator, or device of equivalent or better control that is suitable for dusts and/or aerosols. |
| Personal Protective Equipment: | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). |
| Hands | None required for the normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. |
| Eyes | None required for the normal handling of packaged product. Wear safety glasses as minimum protection if package is open. |
| Skin | None required for the normal handling of packaged product, wear impervious disposable protective clothing if product skin contact expected . |
| Respiratory protection: | None required for normal handling of packaged product. If capsules are crushed or broken Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection. |
| Thermal hazards | Not available. |
| General hygiene considerations | Handle in accordance with good industrial hygiene and safety practice |

Section 9: Physical and Chemical Properties

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|---------------------------------------|--------------------------|
| Physical State | Solid |
| Appearance | Capsules |
| Color | No information available |
| Odor | Unknown |
| pH | Unknown |
| Molecular Formula | Mixture |
| Molecular Weight | Mixture |
| Water Solubility | No data available |
| Solubility (other) | No data available |
| Melting/Freezing Point (°C) | No data available |
| Partition Coefficient (logP): | No data available |
| Decomposition temperature | No data available |
| Evaporation Rate (Gram/s) | No data available |
| Vapor pressure (kPa) | No data available |
| Vapor density (g/ml) | No data available |
| Relative density | No data available |
| Viscosity | No data available |
| Flammability: | |
| Autoignition temperature (Solid) (°C) | No data available |

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|---|-------------------|
| Flammability (Solids) | No data available |
| Flash Point (Liquid) (°C) | No data available |
| Upper Explosive Limits (Liquid) (% by Vol.) | No data available |
| Lower Explosive Limits (Liquid) (% by Vol.) | No data available |

Section 10: Stability and Reactivity

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| Reactivity | Not defined As Reactive substance. |
| Chemical stability | Stable under normal conditions of use. |
| Possibility of Hazardous Reactions: | |
| Oxidizing Properties | No data available |
| Incompatible materials | None known based on information supplied. As a precautionary measure, keep away from strong oxidizers |
| Hazardous Decomposition | No data available |

Section 11: Toxicological Information

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|------------------------|---|
| Product: | No data for this product/Mixture were identified. The following data presents the active ingredient and/or individual ingredients where applicable. |
| Unknown Acute Toxicity | 44.8% of the mixture consists of ingredient(s) of unknown toxicity The following values are calculated based on chapter 3.1 of the GHS document. |
| ATEmix (oral) | 12053 mg/kg |
| ATEmix (dermal) | 4420 mg/kg |

Acute toxicity:

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-----------------------|--------------------|-------------------|-----------------|
| Sesame Oil | N/A | > 2 g/kg (Rabbit) | N/A |
| Ferrous Fumarate | = 3850 mg/kg (Rat) | N/A | N/A |
| Norethindrone Acetate | 6 gm/kg (rat) | N/A | N/A |
| Ethinyl Estradiol | = 960 mg/kg (Rat) | N/A | N/A |

Repeated dose toxicity:

| Chemical Name | Germ cell mutagenicity | Carcinogenicity | Reproductive toxicity | Effects on or via lactation |
|-----------------------|---|-----------------------------|---|---|
| Norethindrone Acetate | Not mutagenic in the standard battery of tests. | Suspected human carcinogen. | May cause irregular vaginal bleeding, decreased libido, and changes in cervical erosion and secretions. | Small amounts of progestin pass into the breast milk, resulting in steroid levels in infant plasma of 1 to 6% of the levels of maternal plasma. Lower infant weight gain, decreased milk production, and decreased composition of nitrogen and protein content of human milk have been associated with norethindrone and estrogenic agents. |

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|-----------------------|--|--|---|--|
| Ethinyl Estradiol | Estradiol induced DNA breaks in hamster renal cells, but not in hepatocytes. | There is sufficient evidence in humans for the carcinogenicity of post-menopausal estrogen therapy. There is sufficient evidence in experimental animals for the carcinogenicity of estradiol and estrone. | Studies in mice show prenatal exposure of ethinylestradiol induces reproductive abnormalities, including polyovular follicles, over-independent vaginal epithelial stratification and cornification. Exposure to ethinylestradiol also is linked to suppression of testicular testosterone levels, lower sperm head counts, lower weights of the testis, epididymis and prostate in rats. | Very small amounts are excreted in milk. |
| Chemical Name | STOT - single exposure | | STOT - repeated exposure | |
| Norethindrone Acetate | No information available. | | Product may irritate exposed tissue, especially if contact is prolonged. | |
| Ethinyl Estradiol | Toxicity is unlikely following acute single exposure of excessive amounts. | Acute poisoning results in mild, self-limiting effects, usually involving the gastrointestinal tract (GI). Chronic toxicity increases risk of cardiovascular disease, including myocardial infarction, cerebrovascular disease, thromboembolic disease, gallbladder disease, and certain cancers in some people. | | |

Chronic toxicity: May cause adverse liver effects. Contains a known or suspected reproductive toxin.
Target Organ Effects: Eyes, Gastrointestinal tract (GI), liver, Reproductive System, Respiratory system, Skin

Section 12: Ecological Information

Environmental Overview: Environmental properties have not been investigated.

Toxicity:

| Chemical Name | Persistence and degradability | Bioaccumulation | Mobility | Partition coefficient |
|----------------------------------|-------------------------------|--------------------------|--------------------------|-----------------------|
| Norethindrone acetate 51-98-9 | No information available | No information available | No information available | N/A |
| Ethinyl Estradiol 57-63-6 | NOT READILY BIODEGRADABLE | No information available | Mobility in soil | 3.67 |

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

The following refers to all modes of transportation unless specified below

Not regulated for transport under USDOT, TDG, ICAO, IATA, IMDG, ADR and ADN regulations.

Section 15: Regulatory Information

TSCA: Not Listed
DSL/NDSL: Listed
EINECS/ELINCS: Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

Carcinogenicity:

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

| Chemical Name | ACGIH | IARC | NTP | OSHA |
|----------------------------------|-------|----------|-----|------|
| Norethindrone Acetate 51-98-9 | - | Group 2B | - | X |
| Ethinyl Estradiol 57-63-6 | - | Group 1 | - | X |

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans; Group 2B - Possibly Carcinogenic to Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labour) X – Present

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

| | |
|--|-----|
| Acute health hazard | Yes |
| Chronic Health Hazard | No |
| Fire hazard | No |
| Sudden release of pressure hazard | No |
| Reactive Hazard | No |

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals

| Name | California Proposition 65 |
|---------------------------------|----------------------------------|
| Norethindrone Acetate - 51-98-9 | Developmental |
| Ethinyl Estradiol - 57-63-6 | Carcinogen Developmental |

U.S. State Right-to-Know Regulations

| Name | New Jersey | Massachusetts | Pennsylvania |
|-------------------|-------------------|----------------------|---------------------|
| Ferrous Fumarate | - | - | X |
| Ethinyl Estradiol | - | X | X |

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.

Slayback Pharma shall not be held liable for any damage resulting from handling or from contact with the above product. Slayback Pharma reserves the right to revise this SDS.