SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Norgestrol OC Tablets 0.075mg
Synonyms: 76C, Opill

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451
Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug – Oral Contraceptive
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Carcinogen Category 2 Reproductive Toxicity Category 1A Effects on or via lactation

DANGER!



Hazard statement(s)
Suspected of causing cancer.
May damage fertility or the unborn child.
May cause harm to breast-fed children.

Precautionary statement(s)
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.

Precautionary statement(s)
Do not breathe dusts.
Avoid contact during pregnancy and while nursing.
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear protective clothing and gloves.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Norgestrel	6533-00-2	<0.2%
Lactose monohydrate	64044-51-5	Proprietary
Microcrystalline Cellulose	9004-34-6	Proprietary
Polacrilin Potassium	65405-55-2	Proprietary
Magnesium Stearate	557-04-0	Proprietary
FD&C Yellow #5 Lake	12225-21-7	Proprietary

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

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air. If irritation or other symptoms occur, get medical attention.
Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: In the case of unintentional ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. The most commonly reported adverse effects associated with therapeutic use of norgestrel alone or in combination with ethinyl estradiol include irregular uterine bleeding, gastrointestinal (GI) effects (*e.g.*, nausea, increased appetite, increased weight), breast tenderness, headache, acne, fatigue, depression, nervousness, and varicose veins. Less frequent albeit more serious adverse effects include serious cardiovascular events and stroke, vascular events, and liver disease.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not generally required. Seek medical advice for unintended exposure.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but will burn under fire conditions. Fine dust from crushed tablets will present a dust explosion hazard.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. If tablets are damaged, respiratory protection may be required. Avoid generating airborne dust during cleanup. If dust is present, eliminate all sources of ignition.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect using methods that avoid the generation of dust and damage to tablets (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly. If dust is present, do not use vacuum unless explosion-proof.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust. If tablets are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging in a secure location.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Norgestrel	0.1 -1 ug/m3 TWA (Perrigo OEB5)
Lactose monohydrate	None Established
Microcrystalline Cellulose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Polacrilin Potassium	None Established
Magnesium Stearate	3 mg/m3 (respirable), 10 mg/m3 (inhalable) TWA ACGIH TLV
FD&C Yellow #5 Lake	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: Impervious gloves recommended for handling damaged tablets.
Eye protection: Chemical safety goggles recommended for handling damaged tablets.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Yellow tablets
Odor: None

Odor threshold: Not applicable	**pH:** Not applicable
Melting point/freezing point: Not applicable	**Boiling Point:** Not applicable
Flash point: Not applicable	**Evaporation rate:** Not applicable
Flammability (solid, gas): Not flammable	**VOC:** Not applicable
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Not applicable	**Vapor density:** Not applicable
Relative density: Not available	**Solubility(ies):** Not available
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of dust may cause irritation of the mucous membranes and upper respiratory tract.
Ingestion: Swallowing amounts above the recommended dose may cause gastrointestinal upset with nausea.
Skin contact: May cause minor irritation.
Eye contact: May cause minor irritation.
Chronic Effects: Clinical use has caused irregular uterine bleeding, gastrointestinal (GI) effects (*e.g.*, nausea, increased appetite, increased weight), breast tenderness, headache, acne, fatigue, depression, nervousness, and varicose veins. Less frequent albeit more serious adverse effects include serious cardiovascular events and stroke, vascular events, and liver disease. Mice and rats were administered levels up to 0.0014% and 0.1% in their diet, respectively, for 80 weeks. No effects were observed in mice, but growth rate and food consumption were decreased in a dose-dependent manner for rats. Dogs were administered oral cyclic doses of up to 0.25 mg/kg for 84 months as a lifetime study. No effects were observed in this long-term study; however, macular eye changes and one or more nodules in the mammary or contiguous tissues were observed at ≥3 µg/kg/day in shorter term studies. Monkeys were administered up to 75 µg/kg for 120 months, and the only adverse effect reported was changes in the eye at 75 µg/kg.
Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.
Germ Cell Mutagenicity: None of the components are germ cell mutagens. Norgestrel was negative in an *in vitro* micronucleus test in mouse bone marrow cells. However, norgestrel was positive in an *in vitro* test in cultured human peripheral blood lymphocytes and an *in vitro* chromosomal aberration test in cultured human lymphocytes. Further, levonorgestrel was negative in a bacterial reverse mutation (Ames) assay, an *in vitro* mammalian culture assay using mouse lymphoma cells and Chinese hamster ovary cells, and an *in vivo* micronucleus assay in mice.
Reproductive Toxicity: May damage fertility or the unborn child. Rats were administered norgestrel at oral doses of 2 µg/day between gestation days 1 and 7 were found to have decreased implantations. In a developmental toxicity study in mice, norgestrel was administered in combination with ethinyl estradiol (no doses specified. A small, dose-related increase in fetal abnormalities (*e.g.*, open eye, cleft palate, fetal brain not encased in the calvarium).
Carcinogenicity: Progestogen-only contraceptives are classified by IARC as group 2B carcinogens. Norgestrel was tested in mice and rats alone or in combination with ethinyl estradiol by oral administration. There was no increase in the incidence of tumors in either species. Further, there was no increase in tumorigenicity following administration of levonorgestrel to rats for 2 years at approximately 5 µg/day, to dogs for 7 years at up to 0.125 mg/kg/day, or to monkeys for 10 years at up to 250 µg/kg/day. None of the other components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values: Not acutely toxic.
Norgestrel: LD50 oral rat >5000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available.
Persistence and degradability: No data available.
Bioaccumulative potential: No data available.
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification.
EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**
CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1* Flammability = 1 Physical Hazard = 0

SDS Revision History: New SDS
Date of preparation: September 14, 2023

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).