# Norplant System

**Product Name:** Norplant System  
**Common Name:** Not available  
**Chemical Name:** Not applicable  
**Synonyms:** Norplant, Levonorgestrel  
**Product Use:** Pharmaceutical product  
**Classification:** Hormones and Synthetic Substitutes  
**Supplier:** Wyeth  
P.O. Box 8299  
Philadelphia, PA 19101 USA.  
Telephone: 1-610-688-4400  
**Emergency Telephone Number:** Chemtrec USA, Puerto Rico, Canada 1-800-424-9300  
Chemtrec International 1-703-527-3887

## 1. PRODUCT AND COMPANY IDENTIFICATION

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## 2. HAZARDS IDENTIFICATION

### Potential Physical Hazards

Powders and solids are presumed to be combustible.

### Potential Health Effects

- **Eyes:** Not available  
- **Skin:** Not available  
- **Inhalation:** Not available  
- **Ingestion:** The most common effects may include uterine bleeding irregularities, change in menstrual flow, breast changes (tenderness, pain, enlargement, secretion, lumps), hirsutism, changes in libido, loss of scalp hair, melasma/chloasma, mood changes, depression, vaginitis, candidiasis, cardiovascular disease, cerebrovascular disease, vascular disease, venous and arterial thrombotic and thromboembolic events, other vascular problems (myocardial infarction, thromboembolism, stroke, hypertension, thromboembolic disorders), hepatic neoplasia, and gallbladder disease.  
- **fibroblast proliferation:** May impair fertility. May cause harm to the unborn child. May cause cancer. Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use.  
- **Therapeutic Target Organ(s):** Reproductive System.

### Potential Environmental Effects

See Section 12.

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**Preparation Date:** 08-Feb-2007  
**Revision Date:** Not applicable  
**Revision Number:** Not applicable
3. COMPOSITION/INFORMATION ON INGREDIENTS

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<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
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<tr>
<td>Levonorgestrel</td>
<td>797-63-7</td>
<td>36 mg/implant</td>
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<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Remainder</td>
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4. FIRST AID MEASURES

**Eye Contact**
In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

**Skin Contact**
Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

**Inhalation**
Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

**Ingestion**
If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

**Flammable Properties**
Presumed to be a combustible particulate solid.

**Extinguishing Media**
- **Suitable Extinguishing Media**
  - Use water spray, foam, dry chemical or carbon dioxide.
- **Unsuitable Extinguishing Media**
  - Do NOT use water jet.

**Fire Fighting**
Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

**Hazardous Combustion Products**
Carbon oxides, nitrogen oxides.

**Protective Equipment and Precautions for Firefighters**
In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions**
Refer to protective measures listed in Sections 7 and 8.

**Environmental Precautions**
Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

**Methods for Containment**
Not available

**Methods for Cleaning up**
Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.
7. HANDLING AND STORAGE

Handling
For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage
No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Exposure Guideline
Levonorgestrel 0.05 mcg/m³

Engineering Controls
Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated. General ventilation shall not be used as the primary control system. Isolators, fume hoods, or biological safety cabinets may be used based on a risk assessment.

Personal Protective Equipment
Eye/face Protection
Provide eye protection based on risk assessment.

Skin Protection
Wear nitrile or latex gloves. Wear protective garment.

Respiratory Protection
Base respirator selection on a risk assessment.

General Hygiene
When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

Other
Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Pharmaceutical implant

Color
Not available

Odor Threshold
Not available

pH
Not applicable

Specific Gravity
Not applicable

Solubility
Not applicable

Partition Coefficient (n-octanol/water)
Not available

Boiling Point
Not applicable

Flash Point
Not available

Melting Point
Not available

Flammability Limits in Air
Upper Not applicable

Explosion Limits
Upper Not applicable

Physical State
Solid

Odor
Not available

Water Solubility
Not available

Evaporation Rate
Not applicable

Vapor Pressure
Not applicable

Autoignition Temperature
Not applicable

Method
None

Lower Not applicable

Upper Not applicable

Lower Not applicable
10. STABILITY AND REACTIVITY

Chemical Stability
Stable at room temperature.

Conditions to Avoid
No data available

Materials to Avoid
No materials to be especially mentioned.

Hazardous Decomposition Products
None under normal use.

Possibility of Hazardous Reactions
None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Levonorgestrel

LD50 Oral > 4000 mg/kg rats
Acute Dermal Irritation Not applicable
Primary Eye Irritation Not applicable
Sensitization Not applicable

Multiple Dose Toxicity

Levonorgestrel

No Toxicologic Effect Not available

Dose/Species/Study Length:

Maximum Tolerated Dose (MTD), Oral

Levonorgestrel

Carcinogenicity Carcinogenicity studies in mice, rats, dogs, or monkeys of racemate, norgestrel, levonorgestrel or combinations of these, resulted in benign and malignant cancers in the breast, liver, and/or pituitary gland. Results of animal studies may not apply to humans because of the major differences in which these species metabolize progestins.

Genetic Toxicity Negative in a battery of genotoxicity tests.
Reproductive Toxicity No data available
Developmental Toxicity In a series of reproductive and developmental studies, no embryotoxic or teratogenic effects were noted.

Levonorgestrel

Target Organ(s) of Toxicity No data available
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Levonorgestrel

- **Mobility**: Not available
- **Biodegradability**: Not readily biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

Ecotoxicity

Levonorgestrel

- **Microorganisms**: Minimum inhibitory concentration (MIC) > 1000 mg/l for 5 test species.
- **Algae**: Not available
- **Daphnia**: LC50/48h/daphnia > 0.94 mg/l, NOEC = 0.94 mg/l
- **Fish**: Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method

Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information

This material is not classified as hazardous for transport.

- **U.S. Department of Transport (DOT)**: Not regulated
- **Canadian Transport of Dangerous Goods (TDG)**: Not regulated
- **International Civil Aviation Organization (ICAO)**: Not regulated
- **International Air Transport Association (IATA)**: Not regulated
- **International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)**: Not regulated
- **Transport of Dangerous Goods by Rail (RID)**: Not regulated
- **Transport of Dangerous Goods by Road (ADR)**: Not regulated
- **Transportation of Dangerous Goods via Inland Waterways (ADN)**: Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)
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 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization
Acute Health Hazard No
Chronic Health Hazard Yes
Fire Hazard No
Sudden Release of Pressure Hazard No
Reactive Hazard No

This product does not contain any HAPs.

State Regulations
California Proposition 65
Listed on Proposition 65.

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Canada
Not classified

WHMIS Hazard Class
Non-controlled

European Union
In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By
Wyeth Department of Environment, Health & Safety
Format
This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References
See Patient Package Insert for more information.
Revision Summary
Not applicable

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End of MSDS