



Norplant System

Preparation Date 08-Feb-2007

Revision Date Not applicable

Revision Number Not applicable

1. PRODUCT AND COMPANY IDENTIFICATION

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

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical implant **Physical State** Solid **Odor** Not available

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.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Reproductive System.

Listed by NTP and IARC. Not listed by OSHA.

Potential Environmental Effects See Section 12.

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Common Name | CAS-No | Composition |
|----------------------|----------------|---------------|
| Levonorgestrel | 797-63-7 | 36 mg/implant |
| Inactive Ingredients | Not applicable | Remainder |

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 Levonorgestrel | Exposure Guideline 0.05 mcg/m ³ |
| 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 Considerations | 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 | Physical State | Solid |
| Color | Not available | Odor | Not available |
| Odor Threshold | Not available | | |
| pH | Not applicable | | |
| Specific Gravity | Not applicable | Water Solubility | Not available |
| Solubility | Not applicable | Evaporation Rate | Not applicable |
| Partition Coefficient (n-octanol/water) | Not available | Vapor Pressure | Not applicable |
| Boiling Point | Not applicable | Autoignition Temperature Method | Not applicable |
| Flash Point | Not available | | None |
| Melting Point | Not available | | |
| Flammability Limits in Air | Upper Not applicable | Lower | Not applicable |
| Explosion Limits | 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.

| Common Name | CAS-No | Type |
|----------------|----------|--------|
| Levonorgestrel | 797-63-7 | Female |

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 |

Disclaimer:

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End of MSDS