

Contraceptive Products

Preparation Date 30-Nov-2006

Revision Date 30-Jan-2008

Revision Number 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Name Contraceptive Products
Common Name Not available
Chemical Name Not applicable
Synonyms Alesse, LoOvral, Lo-Ovral 28 and Ferrous Fumarate (Iron), Lybrel, Ovral, Ethinyl Estradiol, Levonorgestrel, Norgestrel, Minesse, Alesse/Loette, Harmonet, Harmonet-28, Triminulet, Trinordiol 28, Minulet 21, Minulet 28, Microval, Minules, Nordiol 28, Nordiol, Biphasil 28, Biphasil, Biphasic, Estrogen-Progestin Combination Contraceptive (COC), Progestin Only Concentrate, Ange, Gestodone, Min-Ovral, Overette, Nordette, Triphasil

Product Use Classification Pharmaceutical product
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. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Norgestrel	6533-00-2	229-433-5	0.5 mg/tablet	T; N; R40, 60, 61, 64, 50/33; S45, 53, 60, 61
Ethinyl Estradiol	57-63-6	200-342-2	0 - 0.05 mg/tablet	T, N; R40, 50/53, 60, 63; S45, 53, 60
Levonorgestrel	797-63-7	212-349-8	0 - 0.25 mg/tablet	T; R40, 60, 61, 64; S45, 53
Gestodene	60282-87-3	262-145-8	0 - 0.1 mg/tablet	T, N; R40, 50/53, 60, 61, 64; S45, 53, 60, 61
Ferrous Fumarate	141-01-5	205-477-7	0 - 75 mg/tablet	None assigned
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable

3. HAZARDS IDENTIFICATION

Emergency Overview

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

Appearance Pharmaceutical tablet

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.

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.

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

Not flammable

Extinguishing Media

Suitable Extinguishing Media
Unsuitable Extinguishing Media

Use water spray, foam, dry chemical or carbon dioxide.
 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
Gestodene	0.02 mcg/m ³
Levonorgestrel	0.05 mcg/m ³
Norgestrel	0.08 mcg/m ³
Ethinyl Estradiol	0.01 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 tablet	Physical State	Solid
Color	Various	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	Not applicable
Flash Point	Not applicable	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

Ferrous Fumarate

LD50 Oral	3850 mg/kg rats 1570 mg/kg mice
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Gestodene

LD50 Oral	600 mg/kg rats 400 mg/kg mice
Acute Dermal Irritation	Not irritating to rabbit skin.
Primary Eye Irritation	Not applicable
Sensitization	Not a dermal sensitizer in guinea pigs.

Levonorgestrel

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

Norgestrel

LD50 Oral	5010 mg/kg rats
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Ethinyl Estradiol

LD50 Oral	960 mg/kg rats
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity

Ferrous Fumarate

No Toxicologic Effect Dose/Species/Study Length:	Not applicable
---	----------------

Gestodene

No Toxicologic Effect Not available
Dose/Species/Study Length:

Levonorgestrel

No Toxicologic Effect Not available
Dose/Species/Study Length:

Norgestrel

No Toxicologic Effect Not available
Dose/Species/Study Length:

Ethinyl Estradiol

No Toxicologic Effect Not applicable
Dose/Species/Study Length:

Maximum Tolerated Dose (MTD), Oral**Ferrous Fumarate**

Carcinogenicity No data available
Genetic Toxicity No data available
Reproductive Toxicity No data available
Developmental Toxicity No data available

Gestodene

Carcinogenicity Mice, rats and dogs developed benign and malignant neoplasms of the mammary glands, liver and pituitary gland.
Genetic Toxicity Negative in a battery of genotoxicity tests.
Reproductive Toxicity See Developmental Toxicity.
Developmental Toxicity There were no embryotoxic or teratogenic effects reported in a series of reproductive and developmental studies in rats and rabbits in combination with ethinyl estradiol. The compound did not contribute to anti-fertility effects.

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.

Norgestrel

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.

Ethinyl Estradiol

Carcinogenicity Based on tumorigenicity studies in mice, rats, dogs and monkeys, not expected to have any tumorigenic potential relevant to humans in the doses used in oral contraceptive use.

Genetic Toxicity	Regarded as a mutagen and capable of damaging genetic material at low doses.
Reproductive Toxicity	No data available
Developmental Toxicity	Teratogenic studies indicated developmental effects occurred with altered litter size in female rats exposed in the first 4 days of gestation. In mice, an oral dose given later in gestation caused fetal deaths and musculoskeletal deformities.
Ferrous Fumarate	
Target Organ(s) of Toxicity	No data available
Gestodene	
Target Organ(s) of Toxicity	No data available
Levonorgestrel	
Target Organ(s) of Toxicity	No data available
Norgestrel	
Target Organ(s) of Toxicity	No data available
Ethinyl Estradiol	
Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information

Ferrous Fumarate	
Mobility	Not available
Biodegradability	Readily biodegradable.
Stability in Water	Not available
Bioaccumulation	Not available
Gestodene	
Mobility	Not available
Biodegradability	Not readily biodegradable.
Stability in Water	Not available
Bioaccumulation	Not available
Levonorgestrel	
Mobility	Not available
Biodegradability	Not readily biodegradable.
Stability in Water	Not available
Bioaccumulation	Not available
Norgestrel	
Mobility	Not available
Biodegradability	Not readily biodegradable.
Stability in Water	Not available
Bioaccumulation	Not available
Ethinyl Estradiol	
Mobility	Not available
Biodegradability	Inherently biodegradable.
Stability in Water	Not available
Bioaccumulation	Not available

Ecotoxicity**Ferrous Fumarate**

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	Not available

Gestodene

Microorganisms	Not available
Algae	EC50/72h/algae < 1 mg/l
Daphnia	EC50/48h > 7.9 mg/l
Fish	EC50/96h/pimephales promelas < 6.6 mg/l

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

Norgestrel

Microorganisms	Nostoc sp. MIC = 200 mg/l.
Algae	Not available
Daphnia	Not available
Fish	Not available

Ethinyl Estradiol

Microorganisms	Minimum inhibitory concentration (MIC) > 1000 mg/l for 3 test species. Clostridium perfringens MIC = 60 mg/l, Nostoc sp. MIC = 40 mg/l.
Algae	Not available
Daphnia	EC50/48h/daphnia = 5.3 mg/l, NOEC = 2.3 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.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety
Format This MSDS was prepared in accordance with Directive 2001/58/EC.
List of References Bayer Schering Pharma MSDS

16. OTHER INFORMATION**Revision Summary**

Addition to synonyms

Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS