MATERIAL SAFETY DATA SHEET

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

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Material Name: Medroxyprogesterone Acetate Tablets

Trade Name: PROVERA; FARLUTAL; RALOVERA; HYSRON; PRODAFEM
Chemical Family: Synthetic progestogen
Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Tablets
Signal Word: DANGER

Statement of Hazard:
May damage fertility or the unborn child.
Suspected of causing cancer.
Toxic to aquatic life with long lasting effects.

Additional Hazard Information:

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs, reproductive system, developing fetus. Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).

Known Clinical Effects: Adverse effects associated with therapeutic use of medroxyprogesterone acetate include menstrual irregularities, abdominal pain or discomfort weight changes, dizziness, headache, weakness or fatigue, and nervousness. Clinical use of this drug has caused loss of libido, impotence, and development of male characteristics in the female fetus.

EU Indication of danger:
Toxic to reproduction: Category 1
Carcinogenic: Category 3
Dangerous for the Environment

EU Hazard Symbols:

EU Risk Phrases:

2. HAZARDS IDENTIFICATION

R40 - Limited evidence of a carcinogenic effect.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Calcium stearate	1592-23-0	216-472-8	Not Listed	*
Medroxyprogesterone acetate	71-58-9	200-757-9	Carc. Cat.3;R40 Repr. Cat.1;R60-61,R50/53	2.5, 5, or 10 mg***
Maize starch	9005-25-8	232-679-6	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Mineral oil	8012-95-1	232-384-2	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Sorbic acid	110-44-1	203-768-7	Not Listed	*

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water 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, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Calcium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Medroxyprogesterone acetate

Pfizer OEL TWA-8 Hr:	2 $\mu g/m^3$, Skin

Maize starch

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Bulgaria OEL - TWA	10.0 mg/m^3
Czech Republic OEL - TWA	4.0 mg/m^3
Greece OEL - TWA	10 mg/m^3
	5 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	4 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	4 mg/m^3
Spain OEL - TWA	10 mg/m^3

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	10 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m^3
Australia TWA	2.5 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Belgium OEL - TWA	2 mg/m^3
Bulgaria OEL - TWA	1.0 fiber/cm3
	6.0 mg/m^3
	3.0 mg/m^3
Czech Republic OEL - TWA	2.0 mg/m^3
	10 mg/m^3
Denmark OEL - TWA	0.3 fiber/cm3
Finland OEL - TWA	0.5 fiber/cm3
	5 mg/m^3
Greece OEL - TWA	10 mg/m^3
	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	0.8 mg/m^3
Lithuania OEL - TWA	2 mg/m^3
	1 mg/m^3
Netherlands OEL - TWA	0.25 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m^3
	1.0 mg/m^3
Portugal OEL - TWA	2 mg/m^3
Romania OEL - TWA	2 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	2 mg/m^3
	10 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Spain OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	2 mg/m^3
	1 mg/m^3

Mineral oil

ACGIH Threshold Limit Value (TWA)	5 mg/m^3
Australia TWA	5 mg/m^3
Belgium OEL - TWA	5 mg/m^3
Bulgaria OEL - TWA	5.0 mg/m^3
Czech Republic OEL - TWA	5 mg/m^3
Denmark OEL - TWA	1 mg/m^3
Finland OEL - TWA	5 mg/m^3
Greece OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	1 mg/m^3
Netherlands OEL - TWA	5 mg/m^3
OSHA - Final PELS - TWAs:	5 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 mg/m^3
Romania OEL - TWA	5 mg/m^3
Slovakia OEL - TWA	5 ppm
	1 mg/m^3
	5 mg/m^3
Spain OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	1 mg/m^3

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	**Color:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Sorbic acid
Rat Oral LD50 7360 mg/kg
Mouse Oral LD50 3200 mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Medroxyprogesterone acetate
Rat Oral LD50 > 6,400 mg/kg
Mouse Para-periosteal LD50 376 mg/kg
Rat Intraperitoneal LD50 > 400 mg/kg
Rat Subcutaneous LD50 > 8000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Mineral oil
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Medroxyprogesterone acetate
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Medroxyprogesterone acetate
10 Year(s) Monkey Intramuscular 3 mg/kg LOAEL Reproductive system
18 Month(s) Mouse Intramuscular 200 mg/kg NOAEL None identified
24 Month(s) Rat Intramuscular 200 mg/kg NOAEL None identified

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Medroxyprogesterone acetate
Embryo / Fetal Development Rat Intramuscular 3 mg/kg LOAEL Embryotoxicity, Not teratogenic
Embryo / Fetal Development Monkey Intramuscular 25 mg/kg LOAEL Developmental toxicity
Embryo / Fetal Development Rabbit Intramuscular 1 mg/kg LOAEL Developmental toxicity

11. TOXICOLOGICAL INFORMATION

Embryo / Fetal Development Rat Subcutaneous 1 mg/kg LOAEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Sucrose
Bacterial Mutagenicity (Ames) *Salmonella* Negative

Medroxyprogesterone acetate
Bacterial Mutagenicity (Ames) *Salmonella* Negative
Micronucleus Mouse Negative
Chromosome Aberration Rodent germ cell Positive
Sister Chromatid Exchange Rodent Lymphocytes Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Medroxyprogesterone acetate
18 Month(s) Mouse Intramuscular 200 mg/kg/month Not carcinogenic
24 Month(s) Rat Intramuscular 200 mg/kg/month Not carcinogenic
18 Month(s) Dog Intramuscular 0.2 mg/kg LOEL Benign tumors
40 Month(s) Dog Intramuscular 0.3 mg/kg NOAEL Tumors, Mammary gland

Carcinogen Status: See below

Talc (non-asbestiform)
IARC: Group 3 (Not Classifiable)

Medroxyprogesterone acetate
IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Listed

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Medroxyprogesterone acetate
Daphnia magna (Water Flea) EC50 48 Hours 1 mg/L
Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 10 mg/L
Pseudokirchneriella subcapitata (Green Alga) EC50 0.13 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Medroxyprogesterone acetate
Activated sludge EC50 75.4 mg/L

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 waste water 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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T , N
EU Indication of danger: Toxic to reproduction: Category 1
Carcinogenic: Category 3
Dangerous for the Environment

EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:

S36/37 - Wear suitable protective clothing and gloves.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
DANGER
May damage fertility or the unborn child.
Suspected of causing cancer.
Toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

15. REGULATORY INFORMATION

Calcium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	216-472-8

Medroxyprogesterone acetate

California Proposition 65	carcinogen initial date 1/1/90 developmental toxicity initial date 4/1/90
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-757-9

Maize starch

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Lactose NF, monohydrate

Australia (AICS):	Present

Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

Sorbic acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-768-7

Mineral oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-384-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R40 - Limited evidence of a carcinogenic effect
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet