SAFETY DATA SHEET

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

Product Identifier

Material Name: Medroxyprogesterone Acetate Tablets

Trade Name: PROVERA; FARLUTAL; RALOVERA; HYSRON; PRODAFEM
Chemical Family: Synthetic progestogen

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A
Carcinogenicity: Category 2

EU Classification:

EU Indication of danger: Toxic to reproduction: Category 1
Carcinogenic: Category 3

EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger
Hazard Statements: H351 - Suspected of causing cancer
H360FD - May damage fertility. May damage the unborn child.

Precautionary Statements: P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards No data available
Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Maize starch	9005-25-8	232-679-6	Not Listed	Not Listed	*
Medroxyprogesterone acetate	71-58-9	200-757-9	Carc. Cat.3;R40 Repr. Cat.1;R60-61	Carc. 2 (H351) Repr. 1A (H360FD)	2.5, 5, or 10 mg***
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	Not Listed	*
Calcium stearate	1592-23-0	216-472-8	Not Listed	Not Listed	*
Mineral oil	8012-95-1	232-384-2	Not Listed	Not Listed	*

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

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Maize starch

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
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
Switzerland OEL -TWAs	3 mg/m^3

Medroxyprogesterone acetate

Pfizer OEL TWA-8 Hr:	2 µg/m^3, Skin

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
Denmark OEL - TWA	0.3 fiber/cm3
Finland OEL - TWA	0.5 fiber/cm3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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
Switzerland OEL -TWAs	2 mg/m^3

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

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
Vietnam OEL - TWAs	5 mg/m^3

Exposure Controls

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Lactose NF, monohydrate
No data available
Sorbic acid
No data available
Mineral oil
No data available
Calcium stearate
No data available
Maize starch
No data available
Sucrose
No data available
Talc (non-asbestiform)
No data available
Medroxyprogesterone acetate
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

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

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

Sorbic acid
Rat Oral LD50 7360 mg/kg
Mouse Oral LD50 3200mg/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 376mg/kg
Rat Intraperitoneal LD50 > 400mg/kg
Rat Subcutaneous LD50 > 8000mg/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

11. TOXICOLOGICAL INFORMATION

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 Intramuscular3 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 Intramuscular3 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
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)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed

Maize starch

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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

Medroxyprogesterone acetate

CERCLA/SARA 313 Emission reporting	Not Listed
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

Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

Calcium stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	216-472-8

Mineral oil

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-384-2

Sorbic acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.

Carcinogenic: Category 3
Toxic to reproduction: Category 1

R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R40 - Limited evidence of a carcinogenic effect

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 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.
Revision date:	18-Mar-2015
	Product Stewardship Hazard Communication
Prepared by:	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