

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078912911

N/A



# MATERIAL SAFETY DATA SHEET

Revision date: 20-Jan-2010

Version: 2.0

Page 1 of 7

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

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288  
Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: Melengestrol Acetate Liquid Premix

Trade Name:	MGA 500 Liquid Premix
Chemical Family:	Mixture
Intended Use:	Veterinary product used as contraceptive agent

## 2. HAZARDS IDENTIFICATION

Appearance: Colorless viscous liquid.  
Signal Word: DANGER

Statement of Hazard: May damage fertility or the unborn child.

### Additional Hazard Information:

Short Term:	May cause mild eye irritation. May cause mild skin irritation (based on animal data).
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

Known Clinical Effects: Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.

EU Indication of danger: Toxic to reproduction, Category 2

### EU Hazard Symbols:



### EU Risk Phrases:

R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

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.

# MATERIAL SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix  
Revision date: 20-Jan-2010

Page 2 of 7  
Version: 2.0

## 2. HAZARDS IDENTIFICATION

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Melengestrol Acetate	2919-66-6	220-859-7	Repr.Cat.2;R60-61	0.11

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Propylene glycol	57-55-6	200-338-0	Not Listed	*

### Additional Information:

\* Proprietary  
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:** Remove all sources of ignition. Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

## MATERIAL SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix  
Revision date: 20-Jan-2010

Page 3 of 7  
Version: 2.0

**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:** Avoid breathing vapor or mist. 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. Keep out of reach of children.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Propylene glycol

Australia TWA	10 mg/m <sup>3</sup> 150 ppm 474 mg/m <sup>3</sup>
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed

#### Melengestrol Acetate

Pfizer OEL TWA-8 Hr:	50µg/m <sup>3</sup>
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**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.

## MATERIAL SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix  
Revision date: 20-Jan-2010

Page 4 of 7  
Version: 2.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Viscous liquid	Color:	Colorless
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

Solubility: Soluble: Water

Flash Point (Liquid) (°C):	103	Closed cup
Upper Explosive Limits (Liquid) (% by Vol.):	12.5	
Lower Explosive Limits (Liquid) (% by Vol.):	2.6	

### 10. STABILITY AND REACTIVITY

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)

##### Propylene glycol

Mouse Oral LD50 22,000 mg/kg  
Rat Oral LD50 20,000 mg/kg  
Rabbit Dermal LD50 20,800 mg/kg

##### Melengestrol Acetate

Rat Oral LD 50 > 8000 mg/kg  
Rat Dermal LD 50 > 22 mg/kg  
Mouse Intraperitoneal LD 50 > 2500 mg/kg  
Mouse Subcutaneous LD 50 > 5000 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)

##### Propylene glycol

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

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

##### Melengestrol Acetate

28 Day(s) Non-human Primate Oral 1.5 µg/kg/day LOAEL Female reproductive system  
3 Month(s) Non-human Primate Oral 5 µg/kg/day NOAEL  
90 Day(s) Rat Oral 0.015 mg/kg/day LOAEL Female reproductive system

## MATERIAL SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix  
Revision date: 20-Jan-2010

Page 5 of 7  
Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

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

##### Melengestrol Acetate

Reproductive & Fertility	Rat	Oral	>= 60 ug/kg/day	LOAEL	Fertility
Embryo / Fetal Development	Rabbit	Oral	>= 0.8 mg/kg/day	LOAEL	Fetotoxicity, Teratogenic
Fertility & Embryonic Development (Male/Female)	Dog	Oral	0.004 mg/kg/day	LOAEL	Fertility, Fetotoxicity
Embryo / Fetal Development	Rat	Subcutaneous	25 mg/kg/day	LOAEL	Fetotoxicity, Teratogenic

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

##### Melengestrol Acetate

Unscheduled DNA Synthesis	Negative
Direct DNA Interaction	Negative
<i>In Vivo</i> Micronucleus	Negative
Mammalian Cell Mutagenicity	HGPRT Negative

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

##### Melengestrol Acetate

2 Year(s)	Mouse	Oral	0.5 mg/kg/day	LOAEL	Tumors, Female reproductive system
2 Year(s)	Dog	Oral	0.002 mg/kg/day	NOAEL	Not carcinogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 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)

##### Melengestrol Acetate

<i>Daphnia magna</i> (Water Flea)	TAD	EC50	48 Hours	> 2 mg/L
<i>Carassius auratus</i> (Goldfish)	Surrogate	LC50	21 Days	> 1 mg/L

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** 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

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

# MATERIAL SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix  
Revision date: 20-Jan-2010

Page 6 of 7  
Version: 2.0

## 15. REGULATORY INFORMATION

**EU Symbol:** T  
**EU Indication of danger:** Toxic to reproduction, Category 2

**EU Risk Phrases:**  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.

**EU Safety Phrases:**  
S24/25 - Avoid contact with eyes and skin.  
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
DANGER  
May damage fertility or the unborn child.

### Canada - WHMIS: Classifications

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



### **Propylene glycol**

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-338-0

### **Melengestrol Acetate**

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	220-859-7

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R60 - May impair fertility.  
R61 - May cause harm to the unborn child.

**Data Sources:** Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

## MATERIAL SAFETY DATA SHEET

**Material Name: Melengestrol Acetate Liquid Premix**  
**Revision date: 20-Jan-2010**

**Page 7 of 7**  
**Version: 2.0**

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**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

**Prepared by:** Toxicology and 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**