

SAFETY DATA SHEETS

This SDS packet was issued with item:

078912911

N/A

SAFETY DATA SHEET



Revision date: 10-Feb-2014

Version: 3.0

Page 1 of 8

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

Product Identifier

Material Name: Melengestrol Acetate Liquid Premix

Trade Name: MGA 500 Liquid Premix
Chemical Family: Mixture

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

Intended Use: Veterinary product used as contraceptive agent

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Colorless viscous liquid.

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

EU Classification:

EU Indication of danger: Toxic to reproduction, Category 2

EU Symbol: T

EU Risk Phrases:

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger

Hazard Statements: H360 - May damage fertility or the unborn child

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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

SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix
Revision date: 10-Feb-2014

Page 2 of 8
Version: 3.0



Other Hazards

Short Term:

Long Term:

Known Clinical Effects:

Australian Hazard Classification (NOHSC):

Note:

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

Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.

Hazardous Substance. Non-Dangerous Goods.

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	%
Melengestrol Acetate	2919-66-6	220-859-7	Repr.Cat.2;R60-61	Repr.1B (H360)	0.11

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

SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix
Revision date: 10-Feb-2014

Page 3 of 8
Version: 3.0

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: 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.

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

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Releases to the environment should be avoided. Use appropriate personal protective equipment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Propylene glycol

SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix
Revision date: 10-Feb-2014

Page 4 of 8
Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	150 ppm 474 mg/m ³ 10 mg/m ³
Ireland OEL - TWAs	150 ppm 470 mg/m ³ 10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³
Melengestrol Acetate Zoetis OEL TWA 8-hr	50 µg/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).

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:	Viscous liquid	Color:	Colorless
Odor:	Odorless	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
Solubility:	Soluble: Water		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
	No data available		
Melengestrol Acetate			
Predicted 7.4 Log D 4.21			
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		
Flammability:			
Autoignition Temperature (Solid) (°C):		No data available	
Flammability (Solids):		No data available	

SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix
Revision date: 10-Feb-2014

Page 5 of 8
Version: 3.0

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

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: Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

Melengestrol Acetate

Rat Oral LD 50 > 8000 mg/kg
Rat Dermal LD 50 > 22mg/kg
Mouse Intraperitoneal LD 50 > 2500mg/kg
Mouse Subcutaneous LD 50 > 5000mg/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 LOEL Female reproductive system
3 Month(s) Non-human Primate Oral 5 µg/kg/day NOEL
90 Day(s) Rat Oral 0.015 mg/kg/day LOEL Female reproductive system

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

Melengestrol Acetate

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

SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix
Revision date: 10-Feb-2014

Page 6 of 8
Version: 3.0

11. TOXICOLOGICAL INFORMATION

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

Melengestrol Acetate

Unscheduled DNA Synthesis Negative
Direct DNA Interaction Negative
In Vivo 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.

Toxicity:

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

Melengestrol Acetate

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

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Melengestrol Acetate

Predicted 7.4 Log D 4.21

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.

SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix
Revision date: 10-Feb-2014

Page 7 of 8
Version: 3.0

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



Propylene glycol

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	200-338-0

Melengestrol Acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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 and GHS Classification abbreviations mentioned in Section 3

H360 - May damage fertility or the unborn child

Toxic to Reproduction: Category 2

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

Data Sources:

The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

SAFETY DATA SHEET

Material Name: Melengestrol Acetate Liquid Premix
Revision date: 10-Feb-2014

Page 8 of 8
Version: 3.0

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 7 - Handling and Storage. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this 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