SAFETY DATA SHEET



1. Identification

Product identifier Melengestrol Acetate Premix - 100 and 200

Other means of identification

Synonyms MGA Premix * MGA® 100 Premix * MGA® 200

Recommended use Veterinary product used as contraceptive agent

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (US) Zoetis Inc.

10 Sylvan Way

Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison

and Drug Center

1-866-531-8896

Product Support/Technical

Services

1-800-366-5288

Emergency telephone

numbers

CHEMTREC (24 hours): 1-800-424-9300

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

Company Name (EU) Zoetis Belgium S.A.

Mercuriusstraat 20 1930 Zaventem

Belgium

Emergency telephone

number

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

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Carcinogenicity Category 1A

Reproductive toxicity Category 1B

Environmental hazards Not classified.

OSHA defined hazards Combustible dust

Label elements



Signal word Danger

Hazard statement May form combustible dust concentrations in air. May cause cancer. May damage fertility or the

unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Prevent dust accumulation to minimize explosion hazard. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Wear protective gloves/protective clothing/eye protection/face

protection. Observe good industrial hygiene practices.

Response If exposed or concerned: Get medical advice/attention. Take off contaminated clothing and wash

before reuse. In case of fire: Use appropriate media to extinguish.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

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Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Starch		9005-25-8	<3
Mineral oil		8012-95-1	1
Melengestrol Acetate		2919-66-6	<1
Sovbean hulls		Not assigned	

Composition comments

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen

may be necessary.

Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical Skin contact

advice/attention. Get medical advice/attention if you feel unwell. Take off contaminated clothing

and wash before reuse.

Do not rub eyes. Rinse thoroughly with plenty of water for at least 15 minutes and consult a Eye contact

physician. Remove contact lenses, if present and easy to do.

Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without Ingestion

advice from poison control center. Never give anything by mouth to a victim who is unconscious or

is having convulsions.

Most important symptoms/effects, acute and

delayed

Indication of immediate medical attention and special treatment needed

tearing, redness, and discomfort. Coughing. Shortness of breath. Defatting of the skin. Rash. Prolonged exposure may cause chronic effects.

Dusts may irritate the respiratory tract, skin and eyes. Exposed individuals may experience eye

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information

For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust. Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

Unsuitable extinguishing media

Do not use water iet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

equipment/instructions Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Ventilate the contaminated area. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

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Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid the generation of dusts during clean-up. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Use only with adequate ventilation. Prevent dust accumulation to minimize explosion hazard. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Provide appropriate exhaust ventilation at places where dust is formed. All equipment used when handling the product must be grounded. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wear personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wash contaminated clothing before reuse. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep away from heat and sources of ignition. Protect from moisture. Keep containers tightly closed in a dry, cool and well-ventilated place. < 25C / 77F. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis Components	Туре	Value	
Melengestrol Acetate (CAS 2919-66-6)	TWA	50 μg/m³	
US. OSHA Table Z-1 Limits	for Air Contaminants (29 CFR 1910.1000)		
Components	Туре	Value	Form
Mineral oil (CAS 8012-95-1)	PEL	5 mg/m3	Mist.
Starch (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
US. ACGIH Threshold Limit	Values		
Components	Туре	Value	Form
Mineral oil (CAS 8012-95-1)	TWA	5 mg/m3	Inhalable fraction.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	
US. NIOSH: Pocket Guide to	Chemical Hazards		
Components	Туре	Value	Form
Mineral oil (CAS 8012-95-1)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
Starch (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
ogical limit values	No biological exposure limits noted for the	ingredient(s).	
trol banding approach	Not available.		

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Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact

with drug product is possible and for bulk processing operations.

Other Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact

with drug product is possible and for bulk processing operations.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment. Whenever excessive air

contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. 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.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Observe any medical surveillance requirements. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Granular solid.

Solid. Physical state Powder. **Form** Color Not available. Odor Not available. Odor threshold Not available. Not available. Hq Melting point/freezing point Not available. Not available. Initial boiling point and boiling

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Not available.

Flammability limit - upper

(%)

Explosive limit - lower (%) Not available.

Explosive limit - upper (%)Not available.Vapor pressureNot available.Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Insoluble

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available.

Decomposition temperature Not available. **Viscosity** Not available.

Other information

Explosive properties Not explosive. **Oxidizing properties** Not oxidizing.

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Moisture. Keep away from heat, spark, open flames and other

sources of ignition. Minimize dust generation and accumulation.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation Dust may irritate respiratory system. Prolonged inhalation may be harmful.

Skin contact Dust or powder may irritate the skin. Frequent or prolonged contact may defat and dry the skin,

leading to discomfort and dermatitis.

Mineral oil Species: Rabbit

Severity: Mild

Eye contact

Mineral oil

Dust may irritate the eyes.

Species: Rabbit Severity: Moderate

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational

exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Dusts may irritate the respiratory tract, skin and eyes. Exposed individuals may experience eye tearing, redness, and discomfort. Coughing. Shortness of breath. Defatting of the skin. Rash.

Prolonged exposure may cause chronic effects. May cause reproductive effects.

Information on toxicological effects

Acute toxicity Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Components Species Test Results

Melengestrol Acetate (CAS 2919-66-6)

Acute Dermal

LD50 Rat > 22 mg/kg

Intraperitoneal

LD50 Mouse > 2500 mg/kg

Oral

LD50 Rat > 8000 mg/kg

Subcutaneous

LD50 Mouse > 5000 mg/kg

Chronic

Oral

LOAEL Mouse 0.5 mg/kg/day, 2 years (Tumors, Female

reproductive system)

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NOAEL Dog 0.002 mg/kg/day, 2 years (Not

carcinogenic)

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Components Species Test Results

<u>Subacute</u>

Oral

LOAEL Monkey 1.5 µg/kg/day, 28 days (Female

reproductive system)

Subchronic

Oral

LOAEL Rat 0.015 mg/kg/day, 90 days (Female

reproductive system)

Skin corrosion/irritation Serious eye damage/eye irritation Prolonged skin contact may cause temporary irritation.

Direct contact with eyes may cause temporary irritation.

Eye Contact

Mineral oil Species: Rabbit

Severity: Moderate

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicityNo data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Mutagenicity

Melengestrol Acetate Direct DNA Interaction

Result: Negative

In Vivo Micronucleus Result: Negative

Mammalian Cell Mutagenicity

Result: Negative Species: HGPRT

Unscheduled DNA Synthesis

Result: Negative

Carcinogenicity May cause cancer.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Mineral oil (CAS 8012-95-1) Known To Be Human Carcinogen.

Reproductive toxicity May damage fertility or the unborn child.

Developmental effects

Melengestrol Acetate > 0.8 mg/kg/day Embryo / Fetal Development, Fetotoxicity,

Teratogenic Result: LOAEL Species: Rabbit Organ: Oral

0.004 mg/kg/day Fertility & Embryonic Development

(Male/Female), Fertility, Fetotoxicity

Result: LOAEL Species: Dog Organ: Oral **Developmental effects**

Melengestrol Acetate 25 mg/kg/day Embryo / Fetal Development, Fetotoxicity,

Teratogenic Result: LOAEL Species: Rat

Organ: Subcutaneous

Reproductivity

Melengestrol Acetate > 60 ug/kg/day Reproductive & Fertility, Fertility

Result: LOAEL Species: Rat Organ: Oral

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged inhalation may be harmful.

Further information

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause

adverse effects.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Avoid release to the environment.

Components Species **Test Results** Melengestrol Acetate (CAS 2919-66-6)

Acute

> 2 mg/L, 48 Hours EC50 Daphnia magna (Water Flea)

Chronic

LC50 Carassius auratus (Goldfish) > 1 mg/L, 21 Days

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available for this product.

Partition coefficient n-octanol / water (log Kow)

Melengestrol Acetate

4.21, (predicted Log D @ pH 7.4)

Mobility in soil No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions

Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds. waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

None known.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

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14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to

Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No

Delayed Hazard - Yes Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

No

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Not regulated.

US state regulationsCalifornia Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3,

subd. (a))Mineral oil (CAS 8012-95-1)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No

Country(s) or region Inventory name On inventory (yes/no)* Japan Inventory of Existing and New Chemical Substances (ENCS)

Existing Chemicals List (ECL) Korea No

New Zealand Inventory New Zealand No **Philippines** Philippine Inventory of Chemicals and Chemical Substances No

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

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Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the **Further information**

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Disclaimer 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. The information in the sheet was written based on the best knowledge and experience currently

available.

Revision information This document has undergone significant changes and should be reviewed in its entirety.

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