



IN CASE OF EMERGENCY CALL:
National Poison Control 800-222-1222

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Megestrol Acetate Suspension
CAS No: 595-33-5
Chemical Name: 17-Hydroxy-6-methylpregna-4,6-diene-3,20-dione acetate
Chemical Formula: $C_{24}H_{32}O_4$
Molecular Weight: 384.52
Product Use: Anorexia, cachexia, or an unexplained, significant weight loss in patients

Manufacturer's Name: VistaPharm, Inc.
Address: 7265 Ulmerton Road
Largo, FL 33771

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Megestrol Acetate 40gm/mL (active ingredient)

Please refer to current package insert for other components.

3. HAZARDS IDENTIFICATION

WARNING STATEMENT

CAUTION: Contains megestrol acetate, a pharmaceutically active pharmaceutical ingredient intended for clinical use only. This product may pose a health hazard only if exposure occurs to liquid contents, e.g., after spill or leak. Overexposure to megestrol acetate, the active ingredient, may affect the developing fetus and impair fertility. Repeated overexposure may cause an increased risk of cancer based on the results of animal studies. Avoid skin contact, eye contact, and inhalation.

Routes of Absorption: Skin contact, eye contact, inhalation, and accidental ingestion.

Eye and Skin: No data available on skin and eye irritation. Repeated skin contact may cause an allergic skin reaction.

Systemic: As a liquid, the potential for exposure is limited unless the contents are released by spill or breakage. When used clinically, megestrol acetate is considered a developmental toxicant (potentially causes effects on the developing fetus) and reproductive toxicant (potentially causes effects on male and female fertility). May cause cancer based on positive studies in laboratory animals.

Medical Conditions

Aggravated by Exposure: None known or reported.

Occupational Exposure Limit: None currently established by OSHA, NIOSH, or ACGIH for the active ingredient, megestrol acetate.

4. FIRST AID MEASURES

Eye Exposure:	Immediately flush eyes thoroughly with water for at least 15 minutes. If an irritation develops, notify medical personnel and supervisor.
Skin Exposure:	Immediately wash thoroughly with soap and water for 15 minutes. If an irritation develops, notify medical personnel and supervisor.
Inhalation:	Immediately move to fresh air and notify medical personnel and supervisor.
Ingestion:	Notify medical personnel and supervisor. Drink 2-3 glasses of water and contact medical personal.

5. FIRE AND EXPLOSION HAZARD

Flash Point:	Not determined.
Extinguishing Media:	Use water spray, dry chemical, carbon dioxide, foam or material appropriate for fire in surrounding area.
Fire Fighting Procedures	Use self contained breathing apparatus and protective clothing.
Hazardous Combustion Products:	Not determined.

6. ACCIDENTAL RELEASE MEASURES

If Material is Spilled or Released:	If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment. For small spills (such as in a laboratory), soak up material with absorbent, e.g., paper towels, and wash spill area thoroughly with soap and water. For large spills, use an absorbent to soak up the spill and an industrial vacuum cleaner equipped with a high efficiency particulate (HEPA) filter. Dispose of collected material in accordance with applicable waste disposal regulations.
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7. HANDLING AND STORAGE

Handling:	Observe good industrial hygiene practices.
Storage:	Store at controlled temperature of 20° and 25°C (68° to 77°F). Protect from heat.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering Controls:	No special ventilation requirements.
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Personal Protection

Respiratory Protection:	Not normally required unless there is a potential for spillage, breakage or release. For procedures involving larger quantities (grams to kilograms) or aerosol-generating procedures such as spraying or vortexing, an air-purifying respirator with NIOSH/MSHA approval for dusts and mists may be needed.
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Clothing and Eye Protection:	Not normally required unless there is a potential for spillage, breakage or release. Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Wear lab coat or other protective overgarment. Base the choice of protection on the job activity and potential for contact with skin, eyes or face.
Gloves:	Rubber gloves are recommended to minimize potential for skin contact when handling aqueous solutions.
Work Practices:	Wash hands and other areas of skin contact thoroughly after handling this material. Contaminated clothing should be cleaned.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor:	Milky white liquid suspension, lemon lime flavor
Physical State:	Liquid
Melting Point (deg. C):	Approximately 100°C
Boiling Point (deg. C):	Not determined.
Solubility:	Insoluble

10. STABILITY AND REACTIVITY

Chemical Stability:	Yes
Conditions to Avoid:	Freezing, excessive heat, especially fire.
Incompatibility:	None known.
Hazardous Decomposition:	Not known to occur.
Hazardous Polymerization:	Not known to occur.

11. TOXICOLOGICAL INFORMATION

Pharmacological Activity:	Not determined.
Occupational Exposure Limits:	Not determined.
Acute Toxicity:	Like other hormones, not acutely toxic but pharmacologically potent at low doses.
Repeat Dose Toxicity:	Not determined.
Irritation:	Not determined.
Sensitization:	Not determined.
Reproductive Effects:	Not determined.
Genotoxicity:	No data identified on mutagenic potential of the compound.
Carcinogenicity:	Considered a carcinogen based on studies in the rat and dogs.
Clinical Safety:	Not determined.

12. ECOLOGICAL INFORMATION

Persistence and Degradability:	No data available. As a derivative of the naturally occurring steroid hormone, progesterone, megestrol acetate may be persistent in the environment.
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13. WASTE DISPOSAL INFORMATION

All wastes containing the material should be properly labeled. Dispose of any waste residues according to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

14. TRANSPORTATION INFORMATION

Hazard Class: Not assigned as per US DOT or IATA.

UN Number: Not assigned as per US DOT or IATA.

15. REGULATORY INFORMATION

FDA: Megestrol suspension is an approved prescription medication.

Labeling: Shipping containers (in addition to identity) are recommended to contain the following warning:

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TSCA: Megestrol acetate is exempt; all remaining ingredients are listed.

CERCLA, SARA 302, and SARA 313: None of the ingredients of this formulation are listed.

California Proposition 65: The active ingredient, megestrol acetate is listed as a developmental toxicant. None of the other ingredients are listed as developmental, reproductive or carcinogenic hazards.

16. DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: June 2009

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION