MATERIAL SAFETY DATA SHEET

Section I  Company and Material Identification

Product Identification: Megestrol Acetate Suspension

Active Ingredient: Megestrol Acetate 40mg/mL

Chemical Name of Active Ingredient: 
Pregna-4,6-diene-3,20-dione, 17-hydroxy-6-methyl-,acetate; megestrol acetate

201 Delaware Street
Greenville, SC 29605

Emergency Contact: Poison Control Center
1-800-222-1222

The following MSDS applies to the formulated liquid product only (for patient administration). If handling megestrol acetate, consult the MSDS for the active ingredient and take appropriate precautions.

Section II  Product Composition

<table>
<thead>
<tr>
<th>Substance</th>
<th>Chemical Abstract Service #</th>
<th>% (by wt.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Megestrol Acetate</td>
<td>595-33-5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>60-70</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>25-30</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>2-5</td>
</tr>
</tbody>
</table>

All other ingredients are below 1% and are considered non-hazardous under US Hazard Communication regulations and EU Directives on labeling and packaging at these concentrations.
Section III  Health Hazards

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.
Section IV  First Aid Precautions

Eye Contact
Immediately flush eyes thoroughly with water for at least 15 minutes. If an irritation develops, notify medical personnel and supervisor.

Skin Contact
Immediately wash thoroughly with soap and water for 15 minutes. If an irritation develops, contact medical personnel and notify supervisor.

Inhalation
Immediately move to fresh air and notify medical personnel and supervisor.

Ingestion
Immediately notify medical personnel and supervisor. Drink 2-3 glasses of water and contact medical personnel.

Section V  Fire Protection

Flamability/Explosivity
As an aqueous mixture, not considered flammable or explosive.

Extinguishing Media
Use water fog or fire extinguishing media suitable for Class A fires (e.g., multipurpose dry chemical or foam) for the surrounding materials in the fire.

Special Fire Fighting Procedures
Wear full structural fire fighting protective clothing and NIOSH/MSHA-approved positive pressure, self-contained breathing apparatus. Decontaminate after use.

Section VI  Spill and Release Measures

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.
Section VII  Handling and Storage

Avoid contact with skin, eyes or clothing. Store in a well-ventilated area. Wash thoroughly after handling.

Section VIII  Exposure Control/Personal Protection

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. Base the choice of protection on the job activity and potential for contact with eyes or face.

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.

Skin Protection
Not normally required unless there is a potential for spillage, breakage or release. Rubber gloves are recommended to minimize potential for skin contact when handling aqueous solutions. Wear lab coat or other protective overgarment. Base the choice of protection on the job activity and potential for skin contact.

Engineering Controls
Not normally required unless there is a potential for spillage, breakage or release. Handle in a laboratory hood, Biological Safety Cabinet or ventilated enclosure if procedures involve aerosolization.

Other
Wash hands, face and other potentially exposed areas immediately after handling material (especially before eating, drinking, or smoking). Decontaminate all protective equipment after use.
**Section IX  Physical/Chemical Properties**

- **Appearance/Color:** Milky white liquid suspension
- **Molecular Weight:** Not applicable/mixture
- **pH:** 3.5-4.0
- **Boiling Point:** Approx. 100°C
- **Melting Point:** Not applicable/liquid
- **Vapor Pressure:** No data available
- **Solubility in Water:** Already in solution
- **Evaporation Rate:** No data available
- **Specific Gravity:** No data available
- **Vapor Density:** No data available
- **Percent Volatile:** No data available

**Section X  Stability/Reactivity**

- **Stability:** Stable
- **Incompatibility:** Not known
- **Hazardous Polymerization or Decomposition Products:** Not known to occur

**Section XI  Toxicological Information**

The following information is for the active ingredient, megestrol acetate:

**Acute toxicity** – Like other hormones, not acutely toxic but pharmacologically potent at low doses.

**Developmental toxicity** – Considered a developmental toxicant. Pregnant rats treated with megestrol acetate caused feminization of male fetuses.

**Reproductive toxicity** – Considered a reproductive toxicant. Male offspring of megestrol acetate treated females had impaired fertility. No data specific to effects on spermatogenesis for megestrol acetate were identified, although based on pharmacological activity, this effect may potentially occur.

**Genotoxicity** – No data identified on mutagenic potential of the compound

**Carcinogenicity** – Considered a carcinogen based on studies in the rat and dogs.

The other major ingredients are of a low order of acute and chronic toxicity, and are not considered to be reproductive, developmental, mutagenic or carcinogenic hazards.
Section XII  Environmental 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.

Aquatic Toxicity
No data available.

Based on the above information, it is recommended that the product be disposed of in an environmentally safe manner with other pharmaceutical wastes.

Section XIII  Waste Disposal Methods

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.

Section XIV  Transportation Information

Hazard Class
Not assigned as per US DOT or IATA.

UN Number
Not assigned as per US DOT or IATA.
Section XV  Labeling/Regulatory Information

Labeling

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

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.

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.
Section XVI  Other Information

No additional information.

Abbreviations
ACGIH: American Conference of Governmental Industrial Hygienists
CERCLA: Comprehensive Environmental Response Compensation and Liability Act (of 1980)
DOT: Department of Transportation
EU: European Union
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association
OSHA: Occupational Safety and Health Administration
NIOSH: National Institute for Occupational Safety and Health
NTP: National Toxicology Program
PEL: Permissible Exposure Limit
SARA: Superfund Amendments and Reauthorization Act
TSCA: Toxic Substances Control Act
TLV: Threshold Limit Value

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The above information is based on data available to us and is believed to be correct. Since the
information may be applied under conditions beyond our control and with which we may be
unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving
it must make their own determination of the effects, properties and protections which pertain to
their particular conditions.

No representative, warranty, or guarantee, express or implied (including a warranty of fitness or
merchantability for a particular purpose), is made with respect to the materials, the accuracy of
this information, the results to be obtained from the use thereof, or the hazards connected with the
use of the material. Caution should be used in the handling and use of the material because it is
pharmacologically active.