

SAFETY DATA SHEET

Preparation Date: 10/26/2017

Revision Date: 10/26/2017

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: ME104
Product Name: MEGESTROL ACETATE, MICRONIZED, USP

Other means of identification

Synonyms: 17-alpha-Acetoxy-6-dehydro-6-methylprogesterone
 17-Acetoxy-6-methylpregna-4,6-diene-3,20-dione
 17-alpha-Acetoxy-6-methylpregna-4,6-diene-3,20-dione
 17-alpha-Acetoxy-6-methyl-4,6-pregnadiene-3,20-dione
 17-(Acetyloxy)-6-methylpregna-4,6-diene-3,20-dione
 6-Dehydro-6-methyl-17-alpha-acetoxyprogesterone
 17-Hydroxy-6-methylpregna-4,6-diene-3,20-dione acetate
 Megestryl acetate
 6-Methyl-17-alpha-acetoxypregna-4,6-diene-3,20-dione
 6-Methyl-6-dehydro-17-alpha-acetoxyprogesterone
 6-Methyl-delta(sup 6)-dehydro-17-alpha-acetoxyprogesterone
 6-Methyl-6-dehydro-17-alpha-acetylprogesterone
 6-Methyl-17-alpha-hydroxy-delta(sup 6)-progesterone acetate
 6-Methyl-delta(sup 4,6)-pregnadien-17-alpha-ol-3,20-dione acetate

CAS #: 595-33-5
RTECS # TU4075000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Drug. Medication.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Martin LaBenz (West Coast)

Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Carcinogenicity	Category 2
Reproductive toxicity	Category 1A

Label elements

Danger

Hazard statements

Suspected of causing cancer

May damage fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Megestrol Acetate	595-33-5	100

4. FIRST AID MEASURES

First aid measures

General Advice:

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention if irritation occurs.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do not induce vomiting without medical advice. Never give anything by mouth to an

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unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms

May cause eye/skin/respiratory tract irritation
Upset stomach
May cause dyspepsia
May cause abdominal pain, nausea, vomiting, diarrhea
May cause constipation
Flatulence
May cause salivation
Dryness of mouth
Excessive sweating
Skin rash
May cause itching and redness of the skin
Dyspnea (Difficulty breathing and shortness of breath)
May cause hypotension
Hypertension
Chest tightness or pain
Heart palpitations
Heart failure
Central nervous system effects
Seizures
Confusion
Insomnia
May cause depression
May cause hyperglycemia
May cause urinary incontinence
Paresthesia (numbness and tingling of the extremities)
Peripheral neuropathy
Weakness
May cause swelling of the arms, hands, fingers, ankles, feet, legs
May cause hot flashes
May cause impotence and decreased libido
May cause menstrual irregularities in women
May affect the liver
It may affect the blood
May cause alopecia (hair loss)
May cause urinary incontinence
May cause phlebitis
May cause thrombosis, thromboembolism

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO₂). Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide.

Specific hazards: May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Protect from light. Sensitive to light. Store in light-resistant containers.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Megestrol Acetate	595-33-5	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Megestrol Acetate	595-33-5	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Megestrol Acetate	595-33-5	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

- Eye protection:** Goggles or Safety glasses with side-shields
- Skin and body protection:** Long sleeved clothing
Chemical resistant apron
Gloves
- Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
- Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:
Solid

Appearance:
Crystals.

Color:
White.

Odor:
No information available.

Taste
No information available.

Formula:
C₂₄H₃₂O₄

Molecular/Formula weight:
384.51

Flammability:
No information available

Flashpoint (°C/°F):
No information available.

Flash Point Tested according to:
Not available

Autoignition Temperature (°C/°F):
No information available

Lower Explosion Limit (%):
No information available

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Upper Explosion Limit (%):
No information available

Melting point/range(°C/°F):
213-220 °C/415.4-428 °F

Decomposition temperature(°C/°F):
No information available

Boiling point/range(°C/°F):
No information available

Bulk density:
No information available

Density (g/cm3):
No information available

Specific gravity:
No information available

pH:
No information available

Vapor pressure @ 20°C (kPa):
No information available

Evaporation rate:
No information available

Vapor density:
No information available

VOC content (g/L):
No information available

Odor threshold (ppm):
No information available

**Partition coefficient
(n-octanol/water):**
No information available

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Insoluble in water

10. STABILITY AND REACTIVITY

Reactivity

No information available

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Exposure to light. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: Carbon monoxide.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Megestrol Acetate

CAS-No. 595-33-5

LD50/oral/rat = No information available

LD50/oral/mouse = No information available

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LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = No information available

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion May cause upset stomach. May cause abdominal pain, nausea, vomiting, diarrhea. May cause flatulence. May cause weakness. May cause dyspepsia. May cause salivation. May cause dry mouth. May cause excessive sweating. May cause skin rash, redness or itching. It may affect cardiovascular system (hypertension). May affect the cardiovascular system (palpitations). May affect the cardiovascular system (hypotension). May affect respiration (dyspnea - difficulty breathing and shortness of breath). May cause chest pain. May affect behavior/central nervous system (confusion). May affect behavior/central nervous system (convulsions/seizures).

Ingestion: May cause insomnia, impaired cognition, hot flashes, fever, urinary incontinence, phlebitis

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Prolonged or repeated ingestion may cause alopecia. Prolonged or repeated ingestion may cause changes in libido, menstrual irregularities. Chronic exposure may affect the peripheral nervous system (peripheral neuropathy with muscle weakness, paresthesia - a sensation of tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles) generally of the hands and feet

(extremities). Prolonged or repeated ingestion can affect the pancreas and may cause hyperglycemia or Diabetes. Chronic exposure may cause swelling of the hands and feet. Chronic exposure may cause impotence. Chronic exposure via ingestion may affect the liver (hepatomegaly). Prolonged or repeated ingestion may affect the blood (anemia, leukopenia. Prolonged or repeated ingestion may result in cardiomyopathy, heart failure, thrombosis, thromboembolism. May cause constipation. Prolonged repeated ingestion may affect behavior (cause depression).

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Possibly carcinogenic to humans. Suspected of causing cancer.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Megestrol Acetate	595-33-5	Group 2B - Possibly Carcinogenic to Humans - Supplement 7 [1987] Progestins	Not listed	Not listed	Present	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity May damage fertility or the unborn child

Reproductive Effects: May cause adverse reproductive effects
Developmental Effects: May cause adverse developmental effects
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.
STOT - repeated exposure No information available.
Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Megestrol Acetate	595-33-5	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class: No information available
Packing group: No information available
Emergency Response Guide Number: No information available
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No Information available
Description: No information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available

Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

ICAO

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Megestrol Acetate	595-33-5	Not Listed	Not present	Not present	Not present	Not present	Present	Present 209-864-5

U.S. Regulations

Megestrol Acetate
Massachusetts RTK: Present

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

 **WARNING:** This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause birth defects or other reproductive harm. For more information go to www.p65warnings.ca.gov.

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Megestrol Acetate	595-33-5	Not Listed	developmental toxicity	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Megestrol Acetate	595-33-5	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules	TSCA 8(d) -Health and Safety Reporting

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		(SNURS)	
Megestrol Acetate	595-33-5	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class

The classification of this product has not been validated yet

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Megestrol Acetate	595-33-5	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Megestrol Acetate	595-33-5	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Megestrol Acetate	595-33-5	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Megestrol Acetate	595-33-5	No information

EU - CLP (1272/2008)

R-phrase(s)

Not determined

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Megestrol Acetate	595-33-5		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

not determined

16. OTHER INFORMATION

Product code: ME104

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Preparation Date: 10/26/2017
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Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet