



SAFETY DATA SHEET

Megestrol Acetate Oral Suspension USP

1. IDENTIFICATION

Product identifier: Megestrol Acetate Oral Suspension USP

Product Codes: FN1038

NDC Numbers: 0121-1038-10, 0121-1038-40, and 0121-1038-00

Supplier Name and Address: PAI Pharma
1700 Perimeter Road
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug

Restrictions on use: Prescription use only.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Carcinogen Category 2 Reproductive Toxicity Category 1B

Label Elements:

Danger!

Hazard statement(s)

Suspected of causing cancer.

May damage fertility or the unborn child.



Precautionary statement(s)

Obtain special instructions before use.

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

Wear protective clothing and gloves.

IF exposed or concerned: Get medical attention.

Store locked up.

Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Megestrol Acetate	595-33-5	1-5%
Propylene Glycol	57-55-6	Proprietary
Sucrose	57-50-1	Proprietary
Xanthan Gum	11138-66-2	Proprietary
Citric Acid	77-92-9	1-5%
Sodium citrate	6132-04-3	Proprietary

Issue Date: 07/08/2025

Revision Date: New SDS

Revision Number: 01

Sodium benzoate	532-32-1	Proprietary
-----------------	----------	-------------

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdosage, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing may cause diarrhea, insomnia, weakness, or fatigue. May cause adverse reproductive effects. Suspected of causing cancer.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for unintended ingestion or overdosage.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Megestrol Acetate	None Established
Propylene Glycol	10 mg/m ³ TWA AIHA WEEL
Sucrose	10 mg/m ³ TWA ACGIH TLV 5 mg/m ³ (respirable) 15 mg/m ³ (total dust) TWA OSHA PEL
Xanthan Gum	None Established
Citric Acid	None Established
Sodium citrate	None Established
Sodium benzoate	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid	Color: White
Odor: Lemon-lime	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	Particle Characteristics: Not applicable
Flammability: Not flammable	VOC: Not determined
Flammable limits: LEL: Not determined	UEL: Not determined
Vapor pressure: Not determined	Relative Vapor density: Not determined
Relative density: 1.2	Solubility(ies): Soluble
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Kinematic Viscosity: Not available

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION**Acute effects of exposure:**

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and effects similar to ingestion.

Ingestion: Swallowing may cause diarrhea, insomnia, weakness, or fatigue.

Skin contact: May cause mild irritation.

Eye contact: May cause irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. There is no mutagenicity data for Megestrol Acetate.

Reproductive Toxicity: Perinatal/postnatal toxicity studies were performed in rats at doses (0.05 to 12.5 mg/kg). In these low dose studies, the reproductive capability of male offspring of megestrol acetate-treated females was impaired. Similar results were obtained in dogs. Pregnant rats treated with megestrol acetate showed a reduction in fetal weight and number of live births, and feminization of male fetuses. No toxicity data are currently available on male reproduction (spermatogenesis).

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA. Data on carcinogenesis were obtained from studies conducted in dogs, monkeys and rats treated with megestrol acetate. No males were used in the dog and monkey studies. In female beagles, megestrol acetate (0.01, 0.1 or 0.25 mg/kg/day) administered for up to 7 years induced both benign and malignant tumors of the breast. In female monkeys, no tumors were found following 10 years of treatment with 0.01, 0.1 or 0.5 mg/kg/day megestrol acetate. Pituitary tumors were observed in female rats treated with 3.9 or 10 mg/kg/day of megestrol acetate for 2 years. The relationship of these tumors in rats and dogs to humans is unknown.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Megestrol Acetate: LD50 IV mouse 56 mg/kg

Propylene Glycol: LD50 oral rat 21-33.7 g/kg; LD50 dermal rabbit 20.8 g/kg

Citric Acid: LD50 oral mouse 5400 mg/kg; LD50 dermal rat >2000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			

IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification.

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product contains megestrol acetate which is listed as a carcinogen and developmental toxin.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

Issue Date: 07/08/2025

Revision Number: 01

Revision Date: New SDS

SDS Revision History: New SDS.

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.