


## Safety Data Sheet

### Megestrol Acetate Oral Suspension 625mg/5ml (125mg/ml)

#### SECTION 1 IDENTIFICATION

<b>Product identifier</b>	Megestrol Acetate Oral Suspension 625mg/5ml (125mg/ml)
<b>other means of identification</b>	NDC No.: 24979-041-13
<b>Recommended use</b>	Indicated for the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with a diagnosis of acquired immunodeficiency syndrome (AIDS)
<b>Manufacturer</b>	
<b>Company name</b>	TWi Pharmaceuticals, Inc.
<b>Address</b>	3F, No 41, Lane 221, Kang Chien Rd, Taipei, Taiwan.
<b>Telephone</b>	886-2-26573350
<b>Fax</b>	886-2-26573391
<b>E-mail address</b>	QA.Service@twipharma.com
<b>Emergency phone number</b>	1-844-518-2989

#### SECTION 2 HAZARD IDENTIFICATION

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Carcinogenicity: Category 2
<b>Label element</b>	
<b>Code</b>	H351
<b>Signal word</b>	Warning
<b>Pictogram</b>	
<b>Hazard statement</b>	Suspected of causing cancer.  This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, seek medical treatment.
<b>Precautionary statement</b>	
<b>Prevention</b>	Observe good industrial hygiene practices. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	Wash hands after handling. If exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store at 20 – 25 °C (68 - 77°F). Store away from heat. Store away from incompatible materials.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations. Incineration of waste at an approved USEPA incinerator is recommended.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.

## SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

**Product/mixture name** Megestrol Acetate Oral Suspension 625mg/5ml (125mg/ml)

**Active ingredient:**

Chemical Name	Common name/Synonyms	CAS number	%
Pregna-4,6-diene-3,20-dione, 17-(acetyloxy)-6-methyl-	Megestrol Acetate	595-33-5	125mg/ml

## SECTION 4 FIRST-AID MEASURES

**Instructions by routes of exposure**

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Wash with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Wash out mouth. Get medical attention if symptoms occur.

**Most important symptoms/effects, both acute and delayed** The common side effects are weight gain, headache, abdominal pain, diarrhea, nausea, cough, chest pain.

**Immediate medical attention and special treatment** Provide general supportive measures and treat symptomatically. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## SECTION 5 FIRE-FIGHTING MEASURES

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Firefighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## SECTION 6 ACCIDENTAL RELEASE MEASURES

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Ensure adequate ventilation.
<b>Methods and materials for containment and cleanup</b>	<b>Large Spills:</b> Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place into containers. Following product recovery, flush area with water. <b>Small Spills:</b> Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.
<b>Environmental precautions</b>	Prevent further leakage or spillage and avoid discharge into drains, water courses or onto the ground.

## SECTION 7 HANDLING AND STORAGE

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing and dispense in a tight container.
<b>Conditions for safe storage, including any incompatibilities</b>	Store between 20 to 25 °C (68 - 77°F) Keep away from heat.

## SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Ventilation should be matched to conditions.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
<b>Skin protection</b>	
<b>Hand protection</b>	For consumer use, no unusual precautions are necessary.
<b>Other</b>	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.
<b>Respiratory protection</b>	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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.

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	
<b>Physical state</b>	Liquid.
<b>Form</b>	Viscous liquid.
<b>Color</b>	White to creamy-white
<b>Odor</b>	Odorless
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.

<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Sparingly soluble in alcohol. Slightly soluble in ether and fixed oils. Soluble in acetone. Very slightly soluble in chloroform.
<b>Partition coefficient: n-octanol/water</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## SECTION 10 STABILITY AND REACTIVITY

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Carbon oxides

## SECTION 11 TOXICOLOGICAL INFORMATION

### Information on the likely routes of exposure (short-term exposure)

<b>Inhalation</b>	Not expected to be hazardous in final pharmaceutical form.
<b>Skin contact</b>	Not expected to be hazardous in final pharmaceutical form.
<b>Eye contact</b>	Not expected to be hazardous in final pharmaceutical form. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Not expected to be hazardous in final pharmaceutical form. May be harmful if swallowed in large quantities.

### Toxicology (long-term exposure)

<b>Symptoms related</b>	The common side effects are weight gain, headache, abdominal pain, diarrhea, nausea, cough, chest pain.
<b>Carcinogenicity</b>	Pituitary tumors were observed in rats in long term studies. The relationship of these tumors in rats to humans is unknown but should be considered in assessing the risk-to-benefit ratio when prescribing.  In finished product form, risk of occupational exposure is expected to be limited.

### **IARC Monographs. Overall Evaluation of Carcinogenicity**

Pregna-4,6-diene-3,20-dione, 17-(acetyloxy)-6-methyl- (CAS 595-33-5)  
Category: 2A Probably carcinogenic to humans.

### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

#### **Reproductive toxicity**

Pregnancy Category: X There are no adequate animal teratology information available for clinically relevant doses.

Because of the potential for adverse effects on the newborn, nursing should be discontinued.

## **SECTION 12 ECOLOGICAL INFORMATION**

<b>Ecotoxicity</b>	Could be a potential endocrine disruptor in the environment. Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Persistence and degradability</b>	Dispose in accordance with all applicable regulations.
<b>Bioaccumulative potential</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Mobility in soil</b>	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).
<b>Other adverse effects</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## **SECTION 13 DISPOSAL CONSIDERATIONS**

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## **SECTION 14 TRANSPORT INFORMATION**

<b>UN Number</b>	Not hazardous for transport
<b>Proper shipping name</b>	Not hazardous for transport
<b>Transport hazard class(es)</b>	
<b>ADR/RID/AND</b>	Not hazardous for transport
<b>IMDG</b>	Not hazardous for transport
<b>IATA/ICAO</b>	Not hazardous for transport
<b>Packing Group</b>	Not hazardous for transport

**Environmental hazards**                      **Marine Pollutant:** Not available.

**Special precautions for users**

**Subsidiary class**                              Not available.

**Emergency Number**                        Not available.

**ADR/RID labels**                              Not available.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code**

**Technical name**                              Not available.

**Ship type**                                      Not available.

**Annex II**                                        Not available.

**SECTION 15 REGULATORY INFORMATION**

**US federal regulations**                      This material is not listed on the US TSCA 8(b) Inventory, therefore it may only be used for TSCA exempt purposes such as R&D or drug use. Drugs, as that term is defined in the FFDC Act, in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

**SECTION 16 OTHER INFORMATION**

**Issue date**                                      March 25, 2016

**Version #**                                        02

**Disclaimer**                                      TWi Pharmaceutical, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.