



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **Android® C-III (methyltestosterone) capsules**

Product Code • 301870902013; NDC 0187-0902-01

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Males: Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Females: Androgens may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals North America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS Revision 3

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Third Revised Edition

Classification of the substance or mixture

UN GHS • Carcinogenicity 1B
Reproductive Toxicity 1A
Specific Target Organ Toxicity Repeated Exposure 1

Label elements

UN GHS

DANGER



Hazard statements • May cause cancer.

May damage fertility or the unborn child.
 Causes damage to organs - Liver, Endocrine System through prolonged or repeated exposure

Precautionary statements

- Prevention** • Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash thoroughly after handling.
- Response** • IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell. IF exposed or concerned: Get medical advice/attention.
- Storage/Disposal** • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

- UN GHS** • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Methyltestosterone	CAS:58-18-4 EINECS:200-366-3	3.2%	UN GHS Revision 3: Carc. 1b, Repro. 2
Corn starch	CAS:9005-25-8 EINECS:232-679-6	N/A	UN GHS Revision 3: NDA
Gelatin capsule	CAS:9000-70-8 EINECS:232-554-6	N/A	UN GHS Revision 3: Skin Irrit. 2; Eye Irrit. 2A
FD&C Blue #1	NDA	N/A	UN GHS Revision 3: NDA
FD&C Red #40	CAS:25956-17-6 EINECS:247-368-0	N/A	UN GHS Revision 3: NDA

N/A - Designates that the chemical percentage of composition is not available as it is considered a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Normal use of this product does not pose an inhalation hazard. However, during bulk handling should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash, blistering) develops, get medical attention.

Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately if symptoms occur.

Ingestion • If swallowed, seek medical advice immediately and show this container or label.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Notes to Physician • Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • No data available

Hazardous Combustion Products • No data available.

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures • Keep unauthorized personnel away. Clean up spilled tablets and place in sealed container. Avoid breaking tablets or creating dust during clean up.

Environmental precautions

- No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • LARGE SPILLS: Use HEPA vacuum to clean up spill. If HEPA vacuum is not available, dampen spilled tablets with water prior to cleaning up to prevent dust cloud.

Section 7 - Handling and Storage

Precautions for safe handling

Handling • Avoid breaking or crushing tablets. Minimize dust generation and accumulation. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage • Keep tightly closed. Store at controlled room temperature 25°C/77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

Section 8 - Exposure Controls/Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Corn starch (9005-25-8)	TWAs	10 mg/m3 TWA	10 mg/m3 TWAEV (containing no Asbestos and <1% Crystalline silica, total dust)	10 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable dust)	15 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable fraction)

Exposure Control Notations

ACGIH

- Corn starch (9005-25-8): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen)

Exposure controls

Engineering

Measures/Controls

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory

- For bulk handling, the personal breathing protection should be determined based upon a risk assessment and in accordance with local regulations. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face

- No eye protection is required during normal handling.

Hands

- Wear protective gloves when handling bulk product before closed in final packaging.

Skin/Body

- Avoid contact with skin.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	Red capsule.
Color	Red	Odor	Not relevant
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	Not relevant	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Water Solubility	Negligible
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			

Octanol/Water Partition coefficient	No data available		
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Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Hazardous polymerization will not occur.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Light, heat and humidity.

Incompatible materials

- Strong oxidizing agents.

Hazardous decomposition products

- When heated to decomposition, toxic fumes of nitrous oxides, sulfur oxides, hydrogen chloride and carbon oxides may be emitted.

Section 11 - Toxicological Information

Information on toxicological effects

Components	
Methyltestosterone (3.2%)	58-18-4 Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg; Reproductive: Ingestion/Oral-Rat TDLo • 9 mg/kg (15-20D preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Urogenital system</i> ; Ingestion/Oral-Rat TDLo • 4 mg/kg (10D male); <i>Reproductive Effects:Paternal Effects:Prostate, seminal vesicle, Cowper's gland, accessory glands</i> ; Skin-Rat TDLo • 1 mg/kg (1-20D preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Urogenital system</i> ; Tumorigen / Carcinogen: Ingestion/Oral-Man TDLo • 420 mg/kg 4 Year(s)-Continuous; <i>Tumorigenic:Carcinogenic by RTECS criteria; Liver:Tumors</i>

GHS Properties	Classification
Acute toxicity	UN GHS 3 • Classification criteria not met
Skin corrosion/Irritation	UN GHS 3 • Classification criteria not met
Serious eye damage/Irritation	UN GHS 3 • Classification criteria not met
Skin sensitization	UN GHS 3 • Classification criteria not met
Respiratory sensitization	UN GHS 3 • Classification criteria not met
Aspiration Hazard	UN GHS 3 • Classification criteria not met
Carcinogenicity	UN GHS 3 • Carcinogenicity 1B
Germ Cell Mutagenicity	UN GHS 3 • Classification criteria not met
Toxicity for Reproduction	UN GHS 3 • Toxic to Reproduction 1A
STOT-SE	UN GHS 3 • Classification criteria not met
STOT-RE	UN GHS 3 • Specific Target Organ Toxicity Repeated Exposure 1

Target Organs

- Liver, Endocrine System

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected. Exposure to dust from broken tablets may cause irritation.
- Chronic (Delayed)**
 - Repeated and prolonged exposure may cause irritation.

Skin

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Repeated and prolonged exposure may cause irritation.

Eye

- Acute (Immediate)**
 - May cause mild eye irritation with direct contact to eye.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)**
 - May be toxic if ingested in excess of prescription dose.
- Chronic (Delayed)**
 - Repeated and prolonged exposure may affect the endocrine system.

Other

- Chronic (Delayed)**
 - Repeated and prolonged exposure may affect the liver. Symptoms may include yellowing of the skin (jaundice), intense fatigue, loss of appetite, nausea, vomiting, and confusion. Cholestatic hepatitis and jaundice occur with 17-alpha-alkylandrogens at a relatively low dose.

Carcinogenic Effects

- There are rare reports of hepatocellular carcinoma in patients receiving long-term therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases. Geriatric patients treated with androgens may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

Reproductive Effects

- When administered to pregnant women, androgens cause virilization of the external genitalia of the female fetus. This virilization includes clitoromegaly, abnormal vaginal development, and fusion of genital folds to form a scrotal-like structure. The degree of masculinization is related to the amount of drug given and the age of the fetus, and is most likely to occur in the female fetus when the drugs are given in the first trimester.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications • No data available

Inventory					
Component	CAS	Canada DSL	Canada NDSL	EU EINECS	TSCA
FD&C Red #40	25956-17-6	Yes	No	Yes	Yes
Methyltestosterone	58-18-4	No	Yes	Yes	Yes
Corn starch	9005-25-8	Yes	No	Yes	Yes
Gelatin capsule	9000-70-8	Yes	No	Yes	Yes

Canada

Labor			
Canada - WHMIS - Classifications of Substances			
• FD&C Red #40	25956-17-6	Not Listed	
• Gelatin capsule	9000-70-8	Not Listed	
• Corn starch	9005-25-8	Uncontrolled product according to WHMIS classification criteria	
• Methyltestosterone	58-18-4	Not Listed	

United States - California

Environment			
U.S. - California - Proposition 65 - Carcinogens List			
• FD&C Red #40	25956-17-6	Not Listed	
• Gelatin capsule	9000-70-8	Not Listed	
• Corn starch	9005-25-8	Not Listed	
• Methyltestosterone	58-18-4	Not Listed	
U.S. - California - Proposition 65 - Developmental Toxicity			
• FD&C Red #40	25956-17-6	Not Listed	
• Gelatin capsule	9000-70-8	Not Listed	

• Corn starch	9005-25-8	Not Listed
• Methyltestosterone	58-18-4	developmental toxicity, 4/1/1990
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
• FD&C Red #40	25956-17-6	Not Listed
• Gelatin capsule	9000-70-8	Not Listed
• Corn starch	9005-25-8	Not Listed
• Methyltestosterone	58-18-4	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
• FD&C Red #40	25956-17-6	Not Listed
• Gelatin capsule	9000-70-8	Not Listed
• Corn starch	9005-25-8	Not Listed
• Methyltestosterone	58-18-4	Not Listed

Section 16 - Other Information

- Revision Date** • 20/June/2016
- Last Revision Date** • 20/June/2016
- Preparation Date** • 20/June/2016
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