1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Product Name
Androderm Transdermal Patch 2.5MG/Day

Other means of identification
Product Code
FG00054
Synonyms
Andropatch, ATMOS

Recommended use of the chemical and restrictions on use
Recommended Use
Primary hypogonadism, hypogonadotropic hypogonadism (congenital or acquired)

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 medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer
Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address
SDS@Allergan.com

Emergency telephone number
Emergency Telephone
Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification
OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Acute toxicity - Oral</th>
<th>Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Category 1B</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Category 1A</td>
</tr>
</tbody>
</table>

Label elements

Danger

Emergency Overview

Hazard statements
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H330 - Fatal if inhaled
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H350 - May cause cancer
Precautionary statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P284 - Wear respiratory protection
P310 - Immediately call a POISON CENTER or doctor/physician
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P320 - Specific treatment is urgent (see .? on this label)
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P304 + P352 - IF ON SKIN: Wash with plenty of soap and water
P321 - Specific treatment (see supplemental first aid instructions on this label)
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P263 - Avoid contact during pregnancy/while nursing
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/ container to an approved waste disposal plant
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Other Information
Unknown Acute Toxicity
4% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLYCERINE USP (96%)</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>30 - 60*</td>
</tr>
<tr>
<td>ALCOHOL USP</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>30 - 60*</td>
</tr>
<tr>
<td>PURIFIED WATER USP</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>GLYCERYL MONOSTEARATE NF</td>
<td>31566-31-1</td>
<td>250-705-4</td>
<td>1 - 5*</td>
</tr>
<tr>
<td>TESTOSTERONE USP/EP</td>
<td>58-22-0</td>
<td>200-370-5</td>
<td>&lt;0.1*</td>
</tr>
</tbody>
</table>

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

4. FIRST AID MEASURES

First aid measures

General advice

Immediate medical attention is required. If symptoms persist, call a physician.

Eye contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately. If symptoms persist, call a physician.

Skin Contact

Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Wash contaminated clothing before reuse. Wash off immediately with plenty of water. If skin irritation persists, call a physician. Immediate medical attention is not required.

Inhalation

Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Immediate medical attention is not required. Move to fresh air in case of accidental inhalation of vapors. If symptoms persist, call a physician.

Ingestion

Do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. Drink plenty of water. Clean mouth with water and drink afterwards plenty of water. Call a physician.

Chemical Name

TESTOSTERONE USP/EP

Note to physicians

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

Sensitivity to Mechanical Impact: Not impact sensitive.

Sensitivity to Static Discharge: Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective suit.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Use personal protective equipment as required. Keep people away from and upwind of
spill/leak. Evacuate personnel to safe areas.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information.

Methods for containment

Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up

Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly. Soak up with inert absorbent material. Dam up. Pick up and transfer to properly labeled containers. Sweep up and shovel into suitable containers for disposal. After cleaning, flush away traces with water. Take precautionary measures against static discharges.

7. HANDLING AND STORAGE

Advice on safe handling

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Use with local exhaust ventilation.

Storage Conditions

Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Keep containers tightly closed in a cool, well-ventilated place. Keep in properly labeled containers.

Incompatible materials


8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (µg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLYCERINE USP (96%) 56-81-5</td>
<td>N/A</td>
<td>TWA: 15 mg/m³ mist, total particulate TWA: 5 mg/m³ mist, respirable fraction (vacated) TWA: 10 mg/m³ mist, total particulate (vacated) TWA: 5 mg/m³ mist, respirable fraction</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>STEL: 1000 ppm</td>
<td>TWA: 1000 ppm TWA: 1900 mg/m³ (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m³</td>
<td>IDLH: 3300 ppm  TWA: 1000 ppm TWA: 1900 mg/m³</td>
<td>N/A</td>
</tr>
<tr>
<td>GLYCERYL MONOSTEARATE NF 31566-31-1</td>
<td>TWA: 10 mg/m³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m³ respirable particulate matter except stearates of toxic metals</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>TESTOSTERONE USP/EP 58-22-0</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>4</td>
</tr>
</tbody>
</table>

NIOSH IDLH Immediately Dangerous to Life or Health

Other Information

Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the
appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection
No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection
During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection
Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>white</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Appearance</td>
<td>Patch</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point/freezing point</td>
<td>155 °C / 311 °F</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td></td>
</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No information available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>insoluble</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>3.32</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance
Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

Incompatible materials

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>Avoid breathing vapors or</td>
<td>See Symptoms for more</td>
<td>Avoid contact with skin.</td>
<td>See Symptoms for more</td>
</tr>
<tr>
<td></td>
<td>mists.</td>
<td>information.</td>
<td></td>
<td>information.</td>
</tr>
<tr>
<td>GLYCERINE USP (96%)</td>
<td>Oral LD50 = 12600 mg/kg (</td>
<td>Dermal LD50 = &gt; 10 g/kg (</td>
<td>Inhalation LC50 = &gt; 570 mg/m³ (</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat )</td>
<td>Rabbit )</td>
<td>Rat ) 1 h</td>
<td></td>
</tr>
<tr>
<td>ALCOHOL USP</td>
<td>= 7060 mg/kg ( Rat )</td>
<td>N/A</td>
<td>= 124.7 mg/L ( Rat ) 4 h</td>
<td></td>
</tr>
<tr>
<td>PURIFIED WATER USP</td>
<td>&gt; 90 mL/kg ( Rat )</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>TESTOSTERONE USP/EP</td>
<td>1000 mg/kg ( Rat )</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLYCERINE USP (96%)</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.</td>
<td>This product does not contain any known or suspected reproductive hazards.</td>
<td>It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.</td>
</tr>
<tr>
<td>ALCOHOL USP</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>This product is categorized as a Group I by the IARC because of the major metabolite of ethanol, acetaldehyde is carcinogenic in experimental animals.</td>
<td>Studies have shown developmental toxicity, but only at high doses.</td>
<td>No information available</td>
</tr>
<tr>
<td>TESTOSTERONE USP/EP</td>
<td>No information available.</td>
<td>Studies have not been performed to evaluate carcinogenic potential. Testosterone is also known to increase the number of tumors and decrease the degree of differentiation of chemically induced carcinomas of the liver in rats.</td>
<td>Known Reproductive Toxicant. Exposure of a female fetus to androgens may result in varying degrees of virilization. Testosterone suppresses spermatogenesis in rats, dogs and non-human primates, which was reversible on cessation of treatment.</td>
<td>This medication is contraindicated in women who are, or who may become pregnant, or who are breastfeeding, and may cause serious adverse reaction in nursing infants.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>STOT - single exposure</th>
<th>STOT - repeated exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>TESTOSTERONE USP/EP</td>
<td>No information available.</td>
<td>No information available.</td>
</tr>
</tbody>
</table>

Chronic toxicity
Prolonged or repeated exposure increases the risk. Possible risk of irreversible effects. Avoid repeated exposure. May cause adverse effects on the bone marrow and blood-forming system. May cause adverse liver effects. Contains a known or suspected reproductive toxin.

Target Organ Effects
blood, Central nervous system, Endocrine System, Eyes, kidney, liver, Reproductive System, Respiratory system, Skin.
Numerical measures of toxicity - Product Information

Unknown Acute Toxicity
4% of the mixture consists of ingredient(s) of unknown toxicity
The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 10163 mg/kg
ATEmix (dermal) 25025 mg/kg
ATEmix (inhalation-dust/mist) 0.4 mg/l

12. ECOLOGICAL INFORMATION

Ecotoxicity
4.02% of the mixture consists of components(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLYCERINE USP (96%) 56-81-5</td>
<td>N/A</td>
<td>51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static</td>
<td>500: 24 h Daphnia magna mg/L EC50</td>
</tr>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>N/A</td>
<td>100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through 12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static</td>
<td>9268 - 14221: 48 h Daphnia magna mg/L LC50 10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLYCERINE USP (96%) 56-81-5</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>-1.76</td>
</tr>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>-0.32</td>
</tr>
<tr>
<td>TESTOSTERONE USP/EP 58-22-0</td>
<td>No information available</td>
<td>Moderate</td>
<td>No information available</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Other adverse effects
No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods
Disposal of wastes
Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging
Do not reuse container. Dispose of contents/containers in accordance with local regulations.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Hazardous Waste Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>Toxic Ignitable</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT
Not regulated

TDG
Not regulated

ICAO (air)
Not regulated

IATA
Not regulated
15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Legend:</th>
<th>TSCA - United States Toxic Substances Control Act Section 8(b) Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSL/NDSL</td>
<td>Canadian Domestic Substances List/Non-Domestic Substances List</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances</td>
</tr>
</tbody>
</table>

US Federal Regulations

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen.

This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>A3</td>
<td>Group 1</td>
<td>Known</td>
<td></td>
</tr>
</tbody>
</table>

ACGIH (American Conference of Governmental Industrial Hygienists)
A3 - Animal Carcinogen
IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
Group 2A - Probably Carcinogenic to Humans
NTP (National Toxicology Program)
Known - Known Carcinogen
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

- Acute health hazard: Yes
- Chronic Health Hazard: Yes
- Fire hazard: No
- Sudden release of pressure hazard: No
- Reactive Hazard: No

CWA (Clean Water Act)
This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

US State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals.
Chemical Name | California Proposition 65
--- | ---
ALCOHOL USP - 64-17-5 | Carcinogen

### U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLYCERINE USP (96%) 56-81-5</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SODIUM HYDROX 1.0N SOLN 1310-73-2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TESTOSTERONE USP/EP 58-22-0</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Revision Date** 02-Oct-2018

**Revision Note** No information available

**Disclaimer**
The information provided in this Material Safety Data Sheet 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.

**End of Safety Data Sheet**