



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 10

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)

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Carcinogenicity	Category 1B
Reproductive toxicity	Category 1A

Label elements

Emergency Overview

Danger

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

**Appearance** Patch**Physical state** Solid**Odor** Odorless**Chemical Name**
TESTOSTERONE USP/EP**Symptoms**

Gynecomastia and excessive frequency and duration of penile erections and oligospermia at high doses. Hirsutism, male pattern baldness, seborrhea and acne. Retention of sodium, chloride, water, potassium, calcium and inorganic phosphates. Nausea, cholestatic, jaundice, alterations of liver function tests and rarely hepatocellular neoplasms and peliosis hepatis. Suppression of clotting factors, increased or decreased libido, headache, anxiety, depression paresthesia, hypersensitivity and anaphylactoid reactions.

Chemical Name
TESTOSTERONE USP/EP**Medical Conditions Aggravated by Exposure**

Hypersensitivity to testosterone, males with carcinoma of the breast or prostate gland. Women who are or may become pregnant and individuals with serious cardiac, hepatic or renal disease.

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

P302 + 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

P362 - Take off contaminated clothing and wash before reuse

P264 - Wash face, hands and any exposed skin thoroughly after handling

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P285 - In case of inadequate ventilation wear respiratory protection

P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

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

P263 - Avoid contact during pregnancy/while nursing

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

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

*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
Sensitivity to Static Discharge

Not impact sensitive.

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	Acids. Heat. Light. caustic.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

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

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

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

Physical state	Solid	Appearance	Patch
Color	white	Odor	Odorless
Odor threshold	No information available		

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

Other Information

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

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

Acids. Heat. Light. caustic.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure**Acute toxicity**

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
ALCOHOL USP	Avoid breathing vapors or mists.	See Symptoms for more information.	Avoid contact with skin.	See Symptoms for more information.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
GLYCERINE USP (96%)	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m ³ (Rat) 1 h
ALCOHOL USP	= 7060 mg/kg (Rat)	N/A	= 124.7 mg/L (Rat) 4 h
PURIFIED WATER USP	> 90 mL/kg (Rat)	N/A	N/A
TESTOSTERONE USP/EP	1000 mg/kg (Rat)	N/A	N/A

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
GLYCERINE USP (96%)	Not mutagenic in the standard battery of tests.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	This product does not contain any known or suspected reproductive hazards.	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.
ALCOHOL USP	Not mutagenic in the standard battery of tests.	This product is categorized as a Group I by the IARC because of the major metabolite of ethanol, acetaldehyde is carcinogenic in experimental animals.	Studies have shown developmental toxicity, but only at high doses.	No information available
TESTOSTERONE USP/EP	No information available.	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.	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.	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.

Chemical Name	STOT - single exposure	STOT - repeated exposure
TESTOSTERONE USP/EP	No information available.	No information available.

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

Chemical Name	Algae/aquatic plants	Fish	Crustacea
GLYCERINE USP (96%) 56-81-5	N/A	51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static	500: 24 h Daphnia magna mg/L EC50
ALCOHOL USP 64-17-5	N/A	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	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

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

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.

Chemical Name	California Hazardous Waste Status
ALCOHOL USP 64-17-5	Toxic Ignitable

14. TRANSPORT INFORMATION

DOT Not regulated
TDG Not regulated
ICAO (air) Not regulated
IATA Not regulated

IMDG Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Not Listed
DSL/NDSL Not Listed
EINECS/ELINCS Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

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).

Chemical Name	ACGIH	IARC	NTP	OSHA
ALCOHOL USP 64-17-5	A3	Group 1	Known	X
TESTOSTERONE USP/EP 58-22-0	-	Group 2A	-	X

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 Developmental
TESTOSTERONE USP/EP - 58-22-0	Carcinogen

U.S. State Right-to-Know Regulations

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

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