

Product Name: Androgel
Issued: May-07-2014

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Androgel

Synonyms: Androgel gel; Androgel packets; Androgel pump; Androgel 1%; Androgel 1.62%; AndroGel 1% Stick Pack; AndroGel 1% Pump; AndroGel 1.62% Stick Pack; AndroGel 1.62% Pump

List Number: 1023; 1020; 1011; 1021; 1010; 1015; 8462

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Manufactured for:
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-800-255-5162
+1-847-932-7900

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

General Note

Reproductive toxicity	Category 1B	
Carcinogenicity	Category 2	
Flammable liquids		Category 3

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Risk Phrases: R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility
R61 - May cause harm to the unborn child

2.2 Label elements

Product Name: Androgel
Issued: May-07-2014

Section 2. Hazards identification



Signal Word: Danger

Hazard Statements: H226 - Flammable liquid and vapor
H351 - Suspected of causing cancer
H360 - May damage fertility or the unborn child

P202 - Do not handle until all safety precautions have been read and understood
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P403 + P235 - Store in a well-ventilated place. Keep cool

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Ethanol 64-17-5	55-70	Present	F; R11	Flam. Liq. 2 (H226)	No data available
Water 7732-18-5	20-30	Present		Not Hazardous*	No data available
Testosterone 58-22-0	1-2	Present	R40, R60, R61	Carc. 2 (H351) Repr. 1B (H360)	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Product Name: Androgel
Issued: May-07-2014

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: None known from occupational exposure.

Medical Conditions Aggravated by Exposure: None known from occupational exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Keep away from heat, sparks and flame.

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

Environmental Precautions: Should not be released into the environment.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Keep away from ignition sources. Ventilate area. Take up mechanically and collect in suitable container for disposal

Incompatibilities: Strong acids and bases.

Product Name: Androgel
Issued: May-07-2014

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Ethanol 64-17-5	1,900 mg/m ³	None
Water 7732-18-5	Not Applicable	None
Testosterone 58-22-0	2 mcg/m ³	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Ethanol 64-17-5	1000 ppm STEL	STEL: 9500 mg/m ³ TWA: 1900 mg/m ³	960 mg/m ³ TWA	1000 ppm (STEL)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Ethanol 64-17-5	1900 mg/m ³ (STEL) 260 mg/m ³ (TWA)	1910 mg/m ³ (STEL) 1910 mg/m ³ (TWA)	960 mg/m ³ (TWA) 1920 mg/m ³ (STEL)	5760 mg/m ³ (STEL) 1920 mg/m ³ (TWA)

8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: Respiratory protection is not needed during normal product use.

Eyes: Eye protection not required during typical product use conditions.

Gloves: Gloves not required during normal product use conditions.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

Product Name: Androgel
Issued: May-07-2014

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Clear Colorless Gel
Odor:	Alcohol odor.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	21.7
Flash Point Method:	Tag Closed Cup (TCC)
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Not determined.
Partition coefficient: n-octanol/water	Not determined.
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	9000-29000 Flow time > 100 seconds
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

Self-Heating Tendency: Not determined.

10.4. Conditions to avoid

Avoid contact with heat, sparks, open flame, and static discharge.

10.5 Incompatible materials

Product Name: AndroGel
Issued: May-07-2014

Not determined

10.6 Hazardous decomposition products

Carbon oxides

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Unlikely
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Ethanol 64-17-5	LD50 =	3450 6300 7060 5560	mg/kg	Mice Rabbits Rats Guinea Pigs
Testosterone 58-22-0	LD50 >	5000	mg/kg	Mammals

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Reproductive Effects: In humans adverse reproductive effects include: fetal abnormalities, testicular atrophy. Pregnancy Category X : Contraindicated in Pregnancy

Carcinogenicity: In humans, produced tumors of the liver. In animals, produced tumors of the male reproductive system, mammary gland, ovaries, uterus.

Mutagenicity: Not determined.

Aspiration hazard: Not determined

Notes:

- 1. ALD: Approximate lethal dosage**
- 2. LC50: Concentration in air that produces 50% mortality**
- 3. LD50: Oral or dermal dosage that produces 50% mortality**

Section 12. Ecological information

Product Name: Androgel
Issued: May-07-2014

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

- 1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
- 2. LC50: Concentration in water that produces 50% mortality in fish.**
- 3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ICAO/IATA

Status: Regulated

- 14.1. UN Number:** ID8000
14.2. Proper shipping name: Consumer Commodity
14.3. Hazard class: 9
14.4. Packing group: III
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

DOT

Status: Regulated

Product Name: Androgel
Issued: May-07-2014

14.2. Proper shipping name: Consumer commodity
14.3. Hazard class: ORM-D

ADR
Status: Not regulated

IMDG/IMO
Status: Regulated
14.1. UN Number: UN1170
14.2. Proper shipping name: Ethanol solution
14.3. Hazard Class: 3
14.4. Packing group: III

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Ethanol 64-17-5	Present	X	X	Not listed.	X
Water 7732-18-5	Present	X	X	Not listed.	X
Testosterone 58-22-0	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Ethanol 64-17-5	Present	-	X	X	Present	HSR001144
Water 7732-18-5	-	2-(4)-1220	X	X	Present	
Testosterone 58-22-0	-	Present	X	X	Present	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Ethanol	55-70	Not Listed	Not Listed	Not Listed
Water	20-30	Not Listed	Not Listed	Not Listed
Testosterone	1-2	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Ethanol	55-70	No	Not Applicable	Not applicable
Water	20-30	No	Not Applicable	Not applicable
Testosterone	1-2	No	Not Applicable	Not applicable

Product Name: Androgel
Issued: May-07-2014

Immediate Health: Yes
Delayed Health: Yes
Fire: Yes
Sudden Pressure: No
Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:
Health: 1
Fire: 3
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R40 - Limited evidence of a carcinogenic effect , R60 - May impair fertility, R61 - May cause harm to the unborn child

Full text of H-Statements referred to under sections 2 and 3

H226 - Flammable liquid and vapor, H351 - Suspected of causing cancer, H360 - May damage fertility or the unborn child

Document Authored By: Occupational and Environmental Toxicology

Issued: May-07-2014

Supersedes the SDS dated: Aug-17-2011

Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.