



Answers That Matter.

SAFETY DATA SHEET

1. Identification

Product identifier Axiron

Other means of identification

Item Code CT5133, TS1975

Synonym(s) AXIRON CT 2% 1.5 ML TOPICAL SOLUTION * Testosterone Solution 2%

Recommended use Pharmaceutical

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Eli Lilly and Company

Address Lilly Corporate Center
Indianapolis, IN 46285
United States

Telephone Phone: +1-317-276-2000

E-mail lilly_msds@lilly.com

Emergency phone number CHEMTREC: +1-800-424-9300

2. Hazard(s) identification

Physical hazards Flammable liquids Category 2

Health hazards Serious eye damage/eye irritation Category 2A

Carcinogenicity Category 2

Reproductive toxicity Category 1A

Reproductive toxicity Effects on or via lactation

Specific target organ toxicity, single exposure Category 3 narcotic effects

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement

H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation.

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

H362 May cause harm to breast-fed children.

H336 May cause drowsiness or dizziness.

Precautionary statement

Prevention

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

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P233 - Keep container tightly closed.

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P240 - Ground/bond container and receiving equipment.

P241 - Use explosion-proof electrical/ventilating/lighting equipment.

P242 - Use only non-sparking tools.

P243 - Take precautionary measures against static discharge.

P260 - Do not breathe mist or vapor.

P263 - Avoid contact during pregnancy/while nursing.

P264 - Wash thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

Response	P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312 - Call a POISON CENTER or doctor/physician if you feel unwell. P370 + P378 - In case of fire: Use appropriate media for extinction.
Storage	P403 + P233 - Store in a well-ventilated place. Keep container tightly closed. P235 - Keep cool. P405 - Store locked up.
Disposal	P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Testosterone		58-22-0	2.4
Ethanol		64-17-5	60.3
Isopropyl Alcohol		67-63-0	28.8
Other components below reportable levels			8.5

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

General information

PRE-EXISTING MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED BY EXPOSURE: Breast or prostate carcinoma. Pregnant or breast feeding women. Hypersensitivity to any of the ingredients, including alcohol and sunscreens.

Inhalation

Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.

Skin contact

Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.

Eye contact

In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

Ingestion

Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.

Most important symptoms/effects, acute and delayed

Most common adverse reactions with therapeutic administration are skin reactions (incidence >5%) or irritation where applied and increased hematocrit. Exogenous administration of testosterone may lead to azoospermia (zero sperm count). May cause teratogenic effects. Testosterone may cause cancer. May cause drowsiness or dizziness.

5. Fire-fighting measures

Suitable extinguishing media

Water. Carbon dioxide (CO₂). Dry chemical powder.

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

Hazardous decomposition products formed under fire conditions. Vapors are flammable and heavier than air. Vapors may travel across the ground and reach remote ignition sources causing a flashback fire danger. Vapors may form explosive mixtures with air. During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective clothing.

General fire hazards

Highly flammable liquid and vapor.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear suitable protective clothing, gloves and eye/face protection.

Methods and materials for containment and cleaning up
Environmental precautions

Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. Do not vacuum. Remove sources of ignition. Use only non-sparking tools.
Avoid release to the environment.

7. Handling and storage

Precautions for safe handling Wear personal protective equipment. See Section 8 of the SDS for Personal Protective Equipment.
Conditions for safe storage, including any incompatibilities Storage temperature: between 15 C and 25 C.

8. Exposure controls/personal protection

Control parameters

Lilly (LEG)

Components

Components	Type	Value	Form
Testosterone (CAS 58-22-0)	Excursion Limit	2.4 ug/m3	30 minutes
	TWA (12hrs)	0.8 ug/m3	
	TWA (8hrs)	0.9 ug/m3	

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm
Isopropyl Alcohol (CAS 67-63-0)	PEL	980 mg/m3 400 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	1000 ppm
Isopropyl Alcohol (CAS 67-63-0)	STEL	400 ppm
	TWA	200 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm
Isopropyl Alcohol (CAS 67-63-0)	STEL	1225 mg/m3
	TWA	500 ppm 980 mg/m3 400 ppm

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
Isopropyl Alcohol (CAS 67-63-0)	40 mg/l	Acetone	Urine	*

* - For sampling details, please see the source document.

Appropriate engineering controls

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator (eg. glovebag, glovebox), or closed material transfer systems.

General hygiene considerations

GENERAL: For all work environments, wear eye protection and ELIMINATE hand-to-eye contact. Avoid skin contact, wear gloves, and take other appropriate precautions.

Individual protection measures, such as personal protective equipment

Eye/face protection

Goggles. Face-shield.

Skin protection

Hand protection

Wear protective gloves.

Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection

Use an approved respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.

Thermal hazards

Not available.

9. Physical and chemical properties

Appearance	Liquid
Physical state	Liquid.
Form	Liquid.
Color	Colorless
Odor	Alcohol-like
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	> 78
Flash point	53.6 - 60.8 °F (12.0 - 16.0 °C) Tag Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	* See Other Information
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	14 - 35 mPa·s
Other information	The majority of the formulation is ethanol and isopropyl alcohol (approx. 89% by weight). Both alcohols are miscible with water forming a homogenous solution. Povidone is freely soluble in water. The other two ingredients, testosterone and octisalate are both water insoluble. Therefore, if an Axiron solution was mixed with a large volume of water, it is possible that at some point the testosterone and octisalate might precipitate out. The other ingredients however, which make up greater than 90% of the formulation, would be soluble and form a homogeneous solution with the water.
Density	0.78 - 0.86 g/cm ³
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Risk of ignition.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Heat, flames and sparks. Avoid temperatures exceeding the flash point.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions

11. Toxicological information

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Ethanol (CAS 64-17-5)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 5000 mg/kg
<i>Inhalation</i>		
LC50	Rat	124.7 mg/l, 4 h
<i>Oral</i>		
LD50	Rat	7060 mg/kg
Isopropyl Alcohol (CAS 67-63-0)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	12800 mg/kg
<i>Inhalation</i>		
LC50	Rat	19000 ppm, 8 hours
<i>Oral</i>		
LD50	Rat	5045 mg/kg
Testosterone (CAS 58-22-0)		
Acute		
<i>Oral</i>		
LD50	Rat	500 - 2000 mg/kg (Methyltestosterone)
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes eye irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Due to inconclusive data the classification criteria are not met.	
Carcinogenicity	<p>Testosterone has been tested by subcutaneous injection and implantation in mice and rats. In mice, the implant induced cervical-uterine tumors, which metastasized in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatoma. 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.</p> <p>There are rare reports of hepatocellular carcinoma in patients receiving long-term oral therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of tumors in all cases.</p> <p>The ethanol carcinogenicity information reported below only applies when it is consumed in alcoholic beverages. The testosterone carcinogenicity information below is for Androgenic (Anabolic) Steroids.</p>	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Ethanol (CAS 64-17-5)	1 Carcinogenic to humans.	
Testosterone (CAS 58-22-0)	2A Probably carcinogenic to humans.	
US. National Toxicology Program (NTP) Report on Carcinogens		
Ethanol (CAS 64-17-5)	Known To Be Human Carcinogen.	
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
Reproductive toxicity	Causes reproductive effects and fetal harm. Potential for serious adverse reactions in nursing infants. (Testosterone) In animal testing, risk of impaired fertility was shown only after administration of very high doses of this substance. (Ethanol)	
Specific target organ toxicity - single exposure	May cause drowsiness or dizziness.	
Specific target organ toxicity - repeated exposure	Animal studies have reported the following effects: Central nervous system effects. Liver effects. Kidney effects. (Ethanol) Based on available data, the classification criteria are not met.	
Aspiration hazard	No aspiration toxicity classification	

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Ethanol (CAS 64-17-5)			
Other	LC50	Rainbow Trout	13 g/l, 96 hr
<i>Acute</i>			
Algae	EC50	Algae	1450 mg/l, 8 d
Crustacea	LC50	Daphnia	9.3 g/l, 48 hr
Isopropyl Alcohol (CAS 67-63-0)			
Aquatic			
Fish	LC50	Bluegill (<i>Lepomis macrochirus</i>)	> 1400 mg/l, 96 hours
Testosterone (CAS 58-22-0)			
	NOEC	Neosporangiococcum sp. (green algae)	100 µg/l, 20 days
Crustacea	LOEC	Daphnia magna	310 µg/l, 21 days (growth)
	NOEC	Daphnia magna	150 µg/l, 21 days (growth)
Aquatic			
Crustacea	LC50	Calanoid copepod (<i>Acartia tonsa</i>)	5600 µg/l, 48 hours
Fish	LOEC	Medaka, high-eyes (<i>Oryzias latipes</i>)	0.0225 µg/l, 21 days (Methyltestosterone)
		Threespine stickleback (<i>Gasterosteus aculeatus</i>)	0.08 mg/l

Persistence and degradability The product is expected to be biodegradable.

Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)

Ethanol	-0.31
Isopropyl Alcohol	0.05
Testosterone	2.9 - 3.48

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations.

Waste from residues / unused products Not available.

Contaminated packaging Not available.

14. Transport information

DOT

UN number	UN1987
UN proper shipping name	Alcohols, n.o.s. (Ethanol; Isopropyl Alcohol)
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
Packing group	II
Special precautions for user	Not available.
Special provisions	172, B1, IB3, T4, TP1, TP29
Packaging exceptions	4b, 150
Packaging non bulk	203
Packaging bulk	242

IATA

UN number	UN1987
UN proper shipping name	Alcohols, n.o.s. (Ethanol; Isopropyl Alcohol)
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	II

Environmental hazards	Yes
ERG Code	3L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

UN number	UN1987
UN proper shipping name	ALCOHOLS, N.O.S. (Ethanol; Isopropyl Alcohol), MARINE POLLUTANT
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	II
Environmental hazards	
Marine pollutant	Yes
EmS	F-E, S-D
Special precautions for user	Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

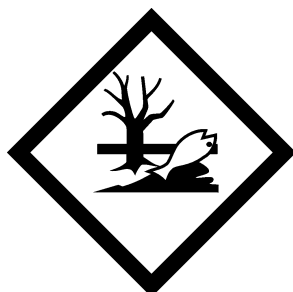
DOT



IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Ethanol (CAS 64-17-5)	Listed.
Isopropyl Alcohol (CAS 67-63-0)	Listed.

SARA 304 Emergency release notification

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
 Immediate Hazard - Yes
 Delayed Hazard - Yes
 Fire Hazard - Yes
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
Isopropyl Alcohol	67-63-0	28.8

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations**US. Massachusetts RTK - Substance List**

Ethanol (CAS 64-17-5)
 Isopropyl Alcohol (CAS 67-63-0)
 Testosterone (CAS 58-22-0)

US. New Jersey Worker and Community Right-to-Know Act

Isopropyl Alcohol (CAS 67-63-0) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

Ethanol (CAS 64-17-5)
 Isopropyl Alcohol (CAS 67-63-0)
 Testosterone (CAS 58-22-0)

US. Rhode Island RTK

Isopropyl Alcohol (CAS 67-63-0)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Ethanol (CAS 64-17-5) Listed: April 29, 2011
 Listed: July 1, 1988
 Testosterone (CAS 58-22-0) Listed: April 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Ethanol (CAS 64-17-5) Listed: October 1, 1987

US - California Proposition 65 - CRT: Listed date/Female reproductive toxin

Testosterone (CAS 58-22-0) Listed: April 1, 1990

US - California Proposition 65 - CRT: Listed date/Male reproductive toxin

Testosterone (CAS 58-22-0) Listed: April 1, 1990

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 02-25-2014

Version # 01

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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Revision Information

Product and Company Identification: Synonyms
Hazards Identification: EU Hazard Classifications
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Transport Information: Proper Shipping Name/Packing Group
Regulatory Information: Risk Phrases - Class.
GHS: Classification

Lilly Lab Code

Health: 2
Fire: 3
Reactivity: 0
Special 1: C
Special 2: R
Special 3: P