

Product Name: LowTiyel
Issued: Feb-22-2017

abbvie
SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name: LowTiyel
Chemical Name: Testosterone
Synonyms: Lowtiyel; Lowtiyel Gel; Lowtiyel Gel; !% Lowtiyel; 1% LowTiyel
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
+1-847-932-7900
Customer Service Telephone: 1-800-255-5162 (US and Canada only) Liquid +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

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Signal Word: Danger

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

Precautionary Statements
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	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. 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.

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.

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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.

6.4. Reference to other sections

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

SECTION 7: Handling and storage

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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: 5000 ppm STEL: 9500 mg/m ³ TWA: 1000 ppm TWA: 1900 mg/m ³	500 ppm TWA 960 mg/m ³ TWA 1000 ppm Peak 1920 mg/m ³ Peak	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)	1000 ppm (STEL) 1910 mg/m ³ (STEL)	500 ppm (TWA) 960 mg/m ³ (TWA) 1000 ppm (STEL) 1920 mg/m ³ (STEL)	3000 ppm (STEL) 5760 mg/m ³ (STEL) 1000 ppm (TWA) 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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Product Name:	LowTiyel
Issued:	Feb-22-2017
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:	Not determined
n-octanol/water	
Autoignition Temp. (°C):	Not determined
Decomposition temperature (°C):	Not determined
Viscosity (centipoise):	9000-29000 Liquid 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

Not determined

10.6. Hazardous decomposition products

Carbon oxides

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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 Liquid Rabbits Liquid Rats Liquid 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 IARC Group 2A (probably carcinogenic to humans).

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

12.1. Toxicity

Not determined

Product Name: LowTiyel
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Chemical Name	Weight-%	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Ethanol 64-17-5	55-70	9268 2		

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 and 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: Not applicable
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

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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
14.6. Special provisions: 2.3.2.2

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	-	-	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	Weight-%	NTP:	IARC:	ACGIH:
Ethanol	55-70	Not listed	Monograph 100E [2012] (in alcoholic beverages); Monograph 96 [2010] (in alcoholic beverages)	A3 - Confirmed Animal Carcinogen with Unknown Relevance to Humans
Water	20-30	Not listed	Not listed	Not listed
Testosterone	1-2	Not listed	Supplement 7 [1987] (listed under Androgenic (anabolic) Steroids)	Not listed

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Ethanol	55-70	No	Not applicable	Not applicable

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Water	20-30	No	Not applicable	Not applicable
Testosterone	1-2	No	Not applicable	Not applicable

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

RCRA Status: Not determined

Proposition 65 Status: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Component	Weight-%	Proposition 65 Listed Materials
Ethanol 64-17-5 (55-70)	55-70	carcinogen, 4/29/2011 (in alcoholic beverages) developmental toxicity, 10/1/1987 (in alcoholic beverages)
Testosterone 58-22-0 (1-2)	1-2	carcinogen, 4/1/1988

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: Feb-22-2017

Supersedes the SDS dated: Sep-18-2014

Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does

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