



Tretinoin Gel

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Tretinoin Gel

Synonyms: Tretinoin Gel 0.01%; Tretinoin Gel 0.025%; Avita® Gel 0.025%

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed. For external use only.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.

Robert J. Coury Global Center

1000 Mylan Blvd.

Canonsburg, PA 15317, USA

+1.724.514.1800

Contact e-mail:

SDScontact@mylan.com

Emergency telephone number

Emergency Telephone:

24 hr. Emergency Contact ChemTel

International: +1-813-248-0585

US & Canada: 1-800-255-3924

Mexico: 800-099-0731

Other Contact Information

FDA Adverse Events Reporting Number:

For reporting adverse health events call:

+1 877-446-3679

2. HAZARDS IDENTIFICATION

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

Classification

Serious eye damage/eye irritation, Category 2A

Reproductive toxicity, Category 1B

Effects on or via lactation, Yes

Acute aquatic toxicity, Category 3

Chronic aquatic toxicity, Category 3

Flammable liquids, Category 2

Label elements

**Signal word:**

Danger

Hazard statements:

H319 - Causes serious eye irritation
 H360 - May damage fertility or the unborn child
 H362 - May cause harm to breast-fed children
 H402 - Harmful to aquatic life
 H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements - Prevention:

Obtain special instructions before use
 Do not handle until all safety precautions have been read and understood
 Use personal protective equipment as required
 Do not breathe dust/fume/gas/mist/vapors/spray
 Avoid contact during pregnancy/while nursing
 Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 Avoid release to the environment
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
 Keep container tightly closed
 Ground/bond container and receiving equipment
 Use only non-sparking tools
 Take precautionary measures against static discharge
 Use explosion-proof electrical/ ventilating/ lighting/ equipment

Precautionary Statements - Response:

IF exposed or concerned: Get medical advice/attention
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Eyes:

If eye irritation persists: Get medical advice/attention

Skin:

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

Fire:

In case of fire: Use CO₂, dry chemical, or foam for extinction

Precautionary Statements - Storage:

Store locked up
 Store in a well-ventilated place. Keep cool

Precautionary Statements - Disposal:

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Other Hazards

No information available.

Unknown acute toxicity

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS**Mixture**

Chemical name	CAS No	Weight-%	Hazard statements
Ethanol	64-17-5	80 - 98%	H225 - Highly flammable liquid and vapor H319 - Causes serious eye irritation
Butylated Hydroxytoluene	128-37-0	< 1%	H302 - Harmful if swallowed H400 - Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects
Tretinoin	302-79-4	< 0.1%	H315 - Causes skin irritation H360 - May damage fertility or the unborn child H362 - May cause harm to breast-fed children H400 - Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects

4. FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Description of first aid measures

Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.

General advice: Show this safety data sheet to the doctor in attendance.

Inhalation: Remove to fresh air.

Skin contact: Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Ingestion: Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider: Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms: Burning sensation, Erythema (skin redness), and Itching.

Chronic symptoms: May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility. May cause harm to breast-fed children.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. FIRE-FIGHTING MEASURES

Extinguishing media

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 hazard: Flammable.

Explosive hazard: Not an explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Hazardous combustion products: Carbon oxides.

Advice for firefighters

Precautionary measures in case of fire: Standard procedure for chemical fires.

Firefighting instructions: Use water spray or fog; do not use straight streams.

Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Other Information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Other Information: Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate

consumer-specific information about this product when used according to the physician's directions.

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep at temperatures below 30°C / 86°F. Keep from freezing. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of reach of children.

Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Control parameters

Exposure Limits:

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves.

Eye/face protection: If splashes are likely to occur, wear safety glasses with side-shields.

Skin and body protection: Wear suitable protective clothing.

Respiratory protection: Use appropriate respiratory protection.

General hygiene considerations: Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	Gel
Color:	Translucent, yellow
Odor:	No data available
Odor threshold:	No data available
pH:	No data available
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
<u>Other Information</u>	
VOC Content (%):	No data available

10. STABILITY AND REACTIVITY**Reactivity**

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION**Information on toxicological effects****Information on likely routes of exposure**

Inhalation: Not an expected route of exposure.

Ingestion: Not an expected route of exposure.

Eye contact: Causes serious eye irritation. (based on components). May cause redness, itching, and pain.

Skin contact: May cause irritation. Prolonged contact may cause redness and irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Burning sensation, Erythema (skin redness), and Itching.

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

Skin corrosion/irritation: May cause skin irritation.

Serious eye damage/eye irritation: Classification based on data available for ingredients. Irritating to eyes.

Respiratory or skin sensitization: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Contains a known or suspected reproductive toxin. May cause harm to breastfed babies.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity

Acute toxicity: No information available

12. ECOLOGICAL INFORMATION**Ecotoxicity**

Harmful to aquatic life with long lasting effects.

Persistence and degradability

No information available.

Bioaccumulation

There is no data for this product.

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

US EPA Waste Number: D001

California Hazardous Waste Status

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

Chemical name	Weight-%	California Hazardous Waste Status
Ethanol (CAS #: 64-17-5)	80 - 98%	Toxic Ignitable

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with DOT / ICAO / IATA / TDG

UN Number

UN 1170

UN proper shipping name

Ethanol solution (Ethyl alcohol solution)

Transport hazard class(es)

Hazard Class: 3



Packing group

II

Environmental hazards

No

Special precautions for user

No information available

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Special Provisions

Shipper, please take note that in addition to limited and/or excepted quantity exemptions, the following Special Provisions may apply to this product.

US DOT: DOT - ORM-D; DOT - 150

TDG: TDG - 150; TDG - 16

IMDG: IMDG - 223; IMDG - 274; IMDG - 955

IATA: IATA - A3

15. REGULATORY INFORMATION

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

International Regulations

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

US Federal Regulations

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.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Right-to-Know Regulations

US State Regulations: This product does not contain any substances regulated by state right-to-know regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Ethanol (CAS #: 64-17-5)	X	X	X
Butylated Hydroxytoluene (CAS #: 128-37-0)	X	X	X

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION

Revision Date: 02-December-2019

Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary

depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:

Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:

Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology

Phone number: +1 304-559-2595

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.

Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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