

Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • Retin-A Gel 0.025%

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

Recommended use • Finished Pharmaceutical Product; For the treatment of acne.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

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 consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Flammable Liquids 3
Eye Irritation 2A
Skin Irritation 2

Label elements

UN GHS

WARNING



Hazard statements • Flammable liquid and vapour
Causes eye irritation
Causes skin irritation

Precautionary statements

Prevention • Do not handle until all safety precautions have been read and understood.
Wash thoroughly after handling.
Use personal protective equipment as required.

- Response** • IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: 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.
If eye irritation persists: Get medical advice/attention.

- Storage/Disposal** • Keep tightly closed. Store below 30°C (86°F), to maintain product integrity. Use before date marked on carton and/or container.
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

- UN GHS** • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Ethanol	CAS:64-17-5 EINECS:200-578-6	> 90%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Muta. 1B; Repr. 1B
Tretinoin	CAS:302-79-4 EINECS:206-129-0	0.025%	UN GHS:
Hydroxypropyl cellulose	CAS:9004-64-2	N/A	UN GHS: NDA
Butylated hydroxytoluene	CAS:128-37-0 EINECS:204-881-4	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 4

The exact percentage of composition has been withheld as a trade secret. N/A - Designates that the chemical percentage of composition is not available as it is considered proprietary information.

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation**
- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.
- Skin**
- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.
- Eye**
- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention. If eye irritation persists: Get medical advice/attention.
- Ingestion**
- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed**Other information**

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures**Extinguishing media**

- Suitable Extinguishing Media** • SMALL FIRES: Dry chemical, CO2, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

- Unsuitable Extinguishing Media** • No data available

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards** • Contains flammable liquid.

- Hazardous Combustion Products** • None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures**

- Personal Precautions** • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

- Emergency Procedures** • Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

- Containment/Clean-up Measures** • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Section 7 - Handling and Storage**Precautions for safe handling**

- Handling** • No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

- Storage** • Keep tightly closed. Store below 30°C (86°F), to maintain product integrity. Use before date marked on carton and/or container. Keep away from sources of ignition – No Smoking.

- Incompatible Materials or Ignition Sources** • None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines • Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Butylated hydroxytoluene (128-37-0)	STELs	Not established	10 mg/m ³ STEV	Not established	Not established
	TWAs	2 mg/m ³ TWA (inhalable fraction and vapor)	Not established	10 mg/m ³ TWA	Not established
Ethanol (64-17-5)	TWAs	Not established	1000 ppm TWAEV; 1880 mg/m ³ TWAEV	1000 ppm TWA; 1900 mg/m ³ TWA	1000 ppm TWA; 1900 mg/m ³ TWA
	STELs	1000 ppm STEL	Not established	Not established	Not established

Exposure Control Notations

ACGIH

- Ethanol (64-17-5): **Carcinogens:** (A3 - Confirmed Animal Carcinogen with Unknown Relevance to Humans)
- Butylated hydroxytoluene (128-37-0): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen)

Exposure controls

Engineering Measures/Controls

- 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 to an acceptable level.

Personal Protective Equipment

Respiratory

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

Hands

- Wear protective gloves .

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

- Wash thoroughly after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Gel	Appearance/Description	Not relevant

Color	Not relevant	Odor	Not relevant
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	Not relevant
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	= 0.81 Water=1 approximately	Water Solubility	No data available
Viscosity	60000 to 150000 Centipoise (cPs, cP) or mPas		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	30 C(86 F)	UEL	19 % (ethanol)
LEL	3.3 % (ethanol)		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze. Protect from light and heat.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Ethanol (> 90%)	64-17-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 7060 mg/kg; <i>Lungs, Thorax, or Respiration</i> : Other changes; Irritation: Eye-Rabbit • 500 mg • Severe irritation; Skin-Rabbit • 20 mg 24 Hour(s) • Moderate irritation
Tretinoin (0.025%)	302-79-4	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg; Reproductive: Skin-Rat TDLo • 55 mg/kg (6-16D preg); <i>Reproductive Effects:Effects on Embryo or Fetus</i> : Fetotoxicity (except death, e.g., stunted fetus)

GHS Properties	Classification
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Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Irritation 2
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2A

Potential Health Effects

Inhalation

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • No data available.

Skin

- Acute (Immediate)** • Causes skin irritation. Topical use may induce severe local erythema and peeling at the site of application. The skin of certain sensitive individuals may become excessively red, edematous, blistered, or crusted.
- Chronic (Delayed)** • No data available.

Eye

- Acute (Immediate)** • May cause mild irritation.
- Chronic (Delayed)** • No data available.

Ingestion

- Acute (Immediate)** • Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)** • No data available.

Carcinogenic Effects

- Carcinogenesis: Long-term animal studies to determine the carcinogenic potential of tretinoin have not been performed. Studies in hairless albino mice suggest that tretinoin may accelerate the tumorigenic potential of weakly carcinogenic light from a solar simulator. In other studies, when lightly pigmented hairless mice treated with tretinoin were exposed to carcinogenic doses of UVB light, the incidence and rate of development of skin tumors was reduced. Due to significantly different experimental conditions, no strict comparison of these disparate data is possible. Although the significance of these studies to man is not clear, patients should avoid or minimize exposure to sun.

Carcinogenic Effects			
	CAS	IARC	NTP
Tretinoin	302-79-4	Not Listed	Evidence of Carcinogenicity
Butylated hydroxytoluene	128-37-0	Group 3-Not Classifiable	Evidence of Carcinogenicity
Ethanol	64-17-5	Group 1-Carcinogenic	Evidence of Carcinogenicity

Reproductive Effects

- Pregnancy: Teratogenic effects. Pregnancy Category C. Oral tretinoin has been shown to be teratogenic in rats when given in doses 1000 times the topical human dose. Oral tretinoin has been shown to be fetotoxic in rats when given in doses 500 times the topical human dose. Topical tretinoin has not been shown to be teratogenic in rats and rabbits when given in doses of 100 and 320 times the topical human dose, respectively (assuming a 50 kg adult applies 250 mg of 0.1% cream topically). However, at these topical doses, delayed ossification of a number of bones occurred

in both species. These changes may be considered variants of normal development and are usually corrected after weaning.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Limited Quantity Shipment	NDA	NDA	NDA
TDG	NDA	Limited Quantity Shipment	NDA	NDA	NDA
IMO/IMDG	NDA	Limited Quantity Shipment	NDA	NDA	NDA
IATA/ICAO	1170	Ethyl alcohol solution	NDA	NDA	NDA

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Other information

- DOT** • DOT 49 CFR 173.150(b). Inner packagings must be less than 1 liter (0.3 gallons). Outer packagings 30 kg (66 lbs) Max. UN Packaging not required.
- TDG** • TDG Part 1.17. Inner packagings must be less than 1 liter (0.3 gallons). Outer packagings 30 kg (66 lbs) Max. UN Packaging not required.
- IMO/IMDG** • IMDG Chapter 3.4. Inner packagings must be less than 1 liter (0.3 gallons). Outer packagings 30 kg (66 lbs) Max. UN Packaging not required.
- IATA/ICAO** • 15 GRAM TUBE ONLY - IATA DGR 2.7. Shipping papers are required. Dangerous goods fees apply. Inner packagings must be 500 ml (16.9 ounces) or less. Outer packagings 1 liter Max. UN Packaging not required. -----
45 GRAM TUBE ONLY - IATA fully regulated material. Shipping papers & UN packaging required. Dangerous goods fees will apply. Inner package limit 0.5 liter

(metal or plastic). Outer package limit 5 liter.

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture****SARA Hazard Classifications** • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Butylated hydroxytoluene	128-37-0	Yes	Yes	Yes
Ethanol	64-17-5	Yes	Yes	Yes
Hydroxypropyl cellulose	9004-64-2	Yes	No	Yes
Tretinoin	302-79-4	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	B2, D2B
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Butylated hydroxytoluene	128-37-0	1 %
• Ethanol	64-17-5	0.1 %
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed

Europe**Other****EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification**

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	F; R11
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	F R:11 S:(2)-7-16
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	S:(2)-7-16
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	carcinogen, initial date 4/29/11 (in alcoholic beverages)
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	developmental toxicity, initial date 10/1/87 (in alcoholic beverages)
• Tretinoin	302-79-4	developmental toxicity, initial date 1/1/89
• Hydroxypropyl cellulose	9004-64-2	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	Not Listed
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	Not Listed
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed

United States - New York**Environment****U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances**

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethanol	64-17-5	Not Listed
• Tretinoin	302-79-4	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed

Section 16 - Other Information**Last Revision Date**

- 19/June/2015

Preparation Date

- 18/June/2015

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