



## Safety Data Sheet

### Section 1: Identification

#### Product identifier

**Product Name**

- **Targretin® (bexarotene) gel 1%**

**Product Code**

- 362856604222; NDC 0187-5525-60

**Product Description**

- Indicated for use in inflammatory skin diseases (atopic dermatitis, allergic contact dermatitis, irritant contact dermatitis, chronic plaque psoriasis)

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

**Recommended use**

- Finished Pharmaceutical Product; Targretin® (bexarotene) gel 1% is indicated for the topical treatment of cutaneous lesions in patients with CTCL (Stage IA and IB) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

**Restrictions on use**

- Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

#### 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**

- Eye Irritation 2A  
Flammable Liquids 2  
Reproductive Toxicity 1  
Skin Irritation 2

#### Label elements

**UN GHS**

**DANGER**



- Hazard statements**
- Highly flammable liquid and vapour
  - Causes skin irritation
  - Causes serious eye irritation
  - May damage fertility or the unborn child.

### Precautionary statements

- Prevention**
- Do not handle until all safety precautions have been read and understood.
  - Wash thoroughly after handling.
  - Keep container tightly closed.
  - Use personal protective equipment as required.
  - Wash : thoroughly after handling.
  - Wear protective gloves and eye/face protection , .
  - Keep away from heat, sparks, open flames and/or hot surfaces. - No smoking.
- 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.
  - If eye irritation persists: Get medical advice/attention.
  - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
  - If skin irritation occurs: Get medical advice/attention.
  - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell.
  - In case of fire: Use appropriate media water spray, foam, dry chemicals, or carbon dioxide for extinction.
  - Wash contaminated clothing before reuse.

- Storage/Disposal**
- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.
  - Store in a well-ventilated place. Keep cool.
  - 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
Bexarotene	CAS:153559-49-0	1%	UN GHS: NDA
Hydroxypropyl cellulose	CAS:9004-64-2	1% TO 5%	UN GHS: NDA
Ethyl alcohol	CAS:64-17-5 EINECS:200-578-6	> 60%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Muta. 1B; Repr. 1B
Polyethylene glycol #400	CAS:25322-68-3	20% TO 40%	UN GHS: NDA

Butylated hydroxytoluene	CAS:128-37-0 EINECS:204-881-4	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 4
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The exact percentage of composition has been withheld as a trade secret. See Section 11 for Toxicological Information.

## Section 4: First-Aid Measures

### Description of first aid measures

- |                   |   |
|-------------------|---|
| <b>Inhalation</b> | <ul style="list-style-type: none"> <li>Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.</li> </ul> |
| <b>Skin</b>       | <ul style="list-style-type: none"> <li>Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse.</li> </ul>  |
| <b>Eye</b>        | <ul style="list-style-type: none"> <li>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.</li> </ul>  |
| <b>Ingestion</b>  | <ul style="list-style-type: none"> <li>If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.</li> </ul>   |

### Most important symptoms and effects, both acute and delayed

- No data available

### Indication of any immediate medical attention and special treatment needed

- |                           |   |
|---------------------------|---|
| <b>Notes to Physician</b> | <ul style="list-style-type: none"> <li>Systemic toxicity following acute overdosage with topical application of Targretin® gel is unlikely because of low systemic plasma levels observed with normal therapeutic doses. There is no specific antidote for overdosage.</li> </ul> |
|---------------------------|---|

### Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Additional details are available on the product package insert or the Physicians Desk Reference.

## Section 5: Fire-Fighting Measures

### Extinguishing media

- |                                     |  |
|-------------------------------------|--|
| <b>Suitable Extinguishing Media</b> | <ul style="list-style-type: none"> <li>SMALL FIRES: Dry chemical, CO<sub>2</sub>, water spray or regular foam.</li> <li>LARGE FIRE: Water spray, fog or regular foam.</li> </ul> |
|-------------------------------------|--|

- |                                       |   |
|---------------------------------------|---|
| <b>Unsuitable Extinguishing Media</b> | <ul style="list-style-type: none"> <li>No data available</li> </ul> |
|---------------------------------------|---|

- |                                |   |
|--------------------------------|---|
| <b>Firefighting Procedures</b> | <ul style="list-style-type: none"> <li>As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.</li> </ul> |
|--------------------------------|---|

### Special hazards arising from the substance or mixture

- |   |  |
|---|--|
| <b>Unusual Fire and Explosion Hazards</b> | <ul style="list-style-type: none"> <li>Some of these materials may burn, but none ignite readily. Flammable/combustible material.</li> </ul> |
|---|--|

- |                                      |   |
|--------------------------------------|---|
| <b>Hazardous Combustion Products</b> | <ul style="list-style-type: none"> <li>No data available</li> </ul> |
|--------------------------------------|---|

### Advice for firefighters

- Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

## Section 6 - Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions**

- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Evacuate immediate area. Ventilate enclosed areas.

**Emergency Procedures**

- ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep unauthorized personnel away. 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.

**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**

- Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete. Refer to Section 13 for appropriate disposal procedures.

**Reference to other sections**

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

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

- Keep away from fire - No Smoking. Keep away from heat and sparks.

**Conditions for safe storage, including any incompatibilities****Storage**

- Keep tightly closed and store in upright position. Store at room temperature 15-30C (59-86F). Solution is flammable, keep away from heat or flame.

**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/m3 STEV	Not established	Not established
	TWAs	2 mg/m3 TWA (inhalable fraction and vapor)	Not established	10 mg/m3 TWA	Not established
Ethyl alcohol (64-17-5)	TWAs	Not established	1000 ppm TWAEV; 1880 mg/m3 TWAEV	1000 ppm TWA; 1900 mg/m3 TWA	1000 ppm TWA; 1900 mg/m3 TWA
	STELs	1000 ppm STEL	Not established	Not established	Not established

**Exposure Control Notations****ACGIH**

- Ethyl alcohol (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**

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

**Personal Protective Equipment****Pictograms****Respiratory**

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor 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**

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. 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**

- Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke during work. Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.

**Environmental Exposure Controls**

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

**Section 9 - Physical and Chemical Properties****Information on Physical and Chemical Properties**

<b>Material Description</b>			
Physical Form	Liquid Gel	Appearance/Description	Not relevant
Color	Not relevant	Odor	Not relevant
Odor Threshold	Not relevant		
<b>General Properties</b>			
Boiling Point	77.8 C(172.04 F)	Melting Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Soluble
Viscosity	3000 to 95000 Centipoise (cPs, cP) or mPas		
<b>Volatility</b>			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available	VOC (Vol.)	67 to 90 %
<b>Flammability</b>			
Flash Point	47 F(8.3333 C) CC (Closed Cup)	UEL	Not relevant
LEL	Not relevant	Burning Time	Not relevant
Autoignition	Not relevant		
<b>Environmental</b>			
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 humidities.

## Possibility of hazardous reactions

- No data available

## Conditions to avoid

- Heat, direct sunlight.

## Incompatible materials

- No data available

## Hazardous decomposition products

- No data available

## Section 11 - Toxicological Information

### Information on toxicological effects

**Other Material Information** • Toxicological information refers to raw materials only. Concentrations and toxicological effects may be substantially reduced in the product.

Components		
Bexarotene (1%)	153559-49-0	<b>Acute Toxicity:</b> Unreported-Mouse TDLo • 100 mg/kg; <b>Tumorigenic:</b> Active as anti-cancer agent; <b>Biochemical:</b> Enzyme inhibition, induction, or change in blood or tissue levels: <b>Other enzymes</b>
Hydroxypropyl cellulose (1% TO 5%)	9004-64-2	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 10200 mg/kg
Ethyl alcohol (> 60%)	64-17-5	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 7060 mg/kg; <b>Lungs, Thorax, or Respiration:</b> Other changes
Polyethylene glycol #400 (20% TO 40%)	25322-68-3	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 28 g/kg
Butylated hydroxytoluene (< 0.1%)	128-37-0	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 890 mg/kg

GHS Properties	Classification
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 • Toxic to Reproduction 1
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.

**Chronic (Delayed)**

- Repeated and prolonged exposure may cause irritation. Retinoids as a class have been associated with photosensitivity.

**Eye****Acute (Immediate)**

- Causes serious eye irritation.

**Chronic (Delayed)**

- No data available.

**Ingestion****Acute (Immediate)**

- May be harmful if swallowed.

**Chronic (Delayed)**

- No data available.

Carcinogenic Effects			
	CAS	IARC	NTP
Butylated hydroxytoluene	128-37-0	Group 3-Not Classifiable	Evidence of Carcinogenicity
Ethyl alcohol	64-17-5	Group 1-Carcinogenic	Evidence of Carcinogenicity

**Reproductive Effects**

- Targretin® gel 1% may cause fetal harm when administered to a pregnant woman. The active ingredient in Targretin, bexarotene, caused malformations when administered orally to pregnant rats during days 7-17 of gestation. Developmental abnormalities included incomplete ossification at 4 mg/kg/day and cleft palate, depressed eye bulge/microphthalmia, and small ears at 16 mg/kg/day. At doses greater than 10 mg/kg/day, bexarotene caused developmental mortality. The no-effect oral dose in rats was 1 mg/kg/day. Plasma bexarotene concentrations in patients with CTCL applying Targretin® gel 1% were generally less than one hundredth the C<sub>max</sub> associated with dysmorphogenesis in rats, although some patients had C<sub>max</sub> levels that were approximately one eighth the concentration associated with dysmorphogenesis in rats.

## 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	ID 8000	Consumer commodity	ORM-D	NDA	NDA
TDG	NDA	NDA	NDA	NDA	NDA
IMO/IMDG	NDA	NDA	NDA	NDA	NDA
IATA/ICAO	ID 8000	Consumer Commodity	9	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

## 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
Bexarotene	153559-49-0	No	No	No
Ethyl alcohol	64-17-5	Yes	Yes	Yes
Hydroxypropyl cellulose	9004-64-2	Yes	No	Yes
Polyethylene glycol #400	25322-68-3	Yes	No	Yes

## Canada

### Labor

#### Canada - WHMIS - Classifications of Substances

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethyl alcohol	64-17-5	B2, D2B
• Hydroxypropyl cellulose	9004-64-2	Uncontrolled product according to WHMIS classification criteria
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

#### Canada - WHMIS - Ingredient Disclosure List

• Butylated hydroxytoluene	128-37-0	1 %
• Ethyl alcohol	64-17-5	0.1 %
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed



## Europe

### Other

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

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethyl alcohol	64-17-5	F; R11
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

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

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethyl alcohol	64-17-5	F R:11 S:(2)-7-16
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

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

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethyl alcohol	64-17-5	S:(2)-7-16
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

## United States

### Environment

#### U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethyl alcohol	64-17-5	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

## United States - California

### Environment

#### U.S. - California - Proposition 65 - Carcinogens List

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethyl alcohol	64-17-5	carcinogen, initial date 4/29/11 (in alcoholic beverages)
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

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

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethyl alcohol	64-17-5	developmental toxicity, initial date 10/1/87 (in alcoholic beverages)
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

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

• Butylated hydroxytoluene	128-37-0	Not Listed
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• Ethyl alcohol	64-17-5	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

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

• Butylated hydroxytoluene	128-37-0	Not Listed
• Ethyl alcohol	64-17-5	Not Listed
• Hydroxypropyl cellulose	9004-64-2	Not Listed
• Bexarotene	153559-49-0	Not Listed
• Polyethylene glycol #400	25322-68-3	Not Listed

## Section 16 - Other Information

**Last Revision Date**

- 11/May/2015

**Preparation Date**

- 11/May/2015

**Disclaimer/Statement of Liability**

- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.