

SAFETY DATA SHEET

1. Identification

Product identifier Onexton (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75%

Other means of identification

Product Code NDC 0187-3050-50

Recommended use Medicinal Product.

Topical treatment of acne vulgaris.

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 medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Company name Valeant Pharmaceuticals International, Inc.
Address 2150 St. Elzéar Blvd. West
 Laval, Quebec H7L 4AB
 Canada
Telephone Customer Support 1-800-321-4576
E-mail Not available.
Emergency phone number 3E Emergency Response 1-866-951-9833
 Hotline

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
BENZOYL PEROXIDE		94-36-0	3.75
CLINDAMYCIN PHOSPHATE		24729-96-2	1.2
CARBOMER		9003-01-4	*
POTASSIUM HYDROXIDE		1310-58-3	*
PROPYLENE GLYCOL		57-55-6	*
WATER		7732-18-5	*

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation

Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact

Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.
Environmental precautions	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

7. Handling and storage

Precautions for safe handling	Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Do not get in eyes, on skin, or on clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Wash contaminated clothing before reuse.
Conditions for safe storage, including any incompatibilities	Prior to dispensing to consumer: Store refrigerated between 2-8°C (36-46°F). Do not freeze. Consumer storage: Store upright at room temperature up to 25°C (77°F).

8. Exposure controls/personal protection

Occupational exposure limits

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

Components	Type	Value
BENZOYL PEROXIDE (CAS 94-36-0)	PEL	5 mg/m ³

US. ACGIH Threshold Limit Values

Components	Type	Value
BENZOYL PEROXIDE (CAS 94-36-0)	TWA	5 mg/m3
POTASSIUM HYDROXIDE (CAS 1310-58-3)	Ceiling	2 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
BENZOYL PEROXIDE (CAS 94-36-0)	TWA	5 mg/m3
POTASSIUM HYDROXIDE (CAS 1310-58-3)	TWA	2 mg/m3

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines**Appropriate engineering controls**

No special controls required during normal clinical use.
When handling bulk product Good general ventilation (typically 10 air changes per hour) 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.

Individual protection measures, such as personal protective equipment**Eye/face protection**

No eye protection required under conditions of intended use.
When handling bulk product: If contact is likely, safety glasses with side shields are recommended.

Skin protection**Hand protection**

No hand protection required under conditions of intended use.
When handling bulk product: For prolonged or repeated skin contact use suitable protective gloves.

Other

No special precautions needed under conditions of intended use.
When handling bulk product: Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No respiratory protection required under conditions of intended use.
When handling bulk product: Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties**Appearance****Physical state**

Aqueous Gel.

Form

Gel.

Color

Opaque white to off-white.

Odor

Not available.

Odor threshold

Not available.

pH

4.5 - 6.5

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	> 20000 cps
Other information	
Specific gravity	> 1

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	To enhance product stability, store at refrigerated temperatures. Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Acids. Bases.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Causes skin irritation. May cause sensitization by skin contact. Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation.

Information on toxicological effects

Acute toxicity May cause an allergic skin reaction.

Components	Species	Test Results
BENZOYL PEROXIDE (CAS 94-36-0)		
Acute		
<i>Oral</i>		
LD50	Rat	7710 mg/kg
<i>Other</i>		
LD50	Mouse	206 mg/kg

Components	Species	Test Results
POTASSIUM HYDROXIDE (CAS 1310-58-3)		
Acute		
<i>Oral</i>		
LD50	Rat	273 mg/kg
PROPYLENE GLYCOL (CAS 57-55-6)		
Acute		
<i>Oral</i>		
LD50	Dog	19 g/kg
	Guinea pig	18.4 g/kg
	Mouse	23.9 g/kg
	Rabbit	18 g/kg
	Rat	30 g/kg
<i>Other</i>		
LD50	Mouse	6630 mg/kg
	Rat	6423 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Respiratory or skin sensitization	
Respiratory sensitization	Not available.
Skin sensitization	May cause an allergic skin reaction.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Carcinogenic effects are not expected as a result of occupational exposure.
IARC Monographs. Overall Evaluation of Carcinogenicity	
BENZOYL PEROXIDE (CAS 94-36-0)	3 Not classifiable as to carcinogenicity to humans.
CARBOMER (CAS 9003-01-4)	3 Not classifiable as to carcinogenicity to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not available.
Chronic effects	Prolonged inhalation may be harmful.
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity	Very toxic to aquatic life.		
Components	Species	Test Results	
POTASSIUM HYDROXIDE (CAS 1310-58-3)			
Aquatic			
Fish	LC50	Western mosquitofish (<i>Gambusia affinis</i>)	80 mg/l, 96 hours
PROPYLENE GLYCOL (CAS 57-55-6)			
Aquatic			
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	> 10000 mg/l, 48 hours

Components	Species	Test Results
Fish	LC50	Fathead minnow (Pimephales promelas) 710 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

BENZOYL PEROXIDE	3.46
PROPYLENE GLYCOL	-0.92

Mobility in soil

Mobility in general

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

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)

POTASSIUM HYDROXIDE (CAS 1310-58-3) Listed.

SARA 304 Emergency release notification

Not regulated.

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 - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
BENZOYL PEROXIDE	94-36-0	3.75

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. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

BENZOYL PEROXIDE (CAS 94-36-0)

POTASSIUM HYDROXIDE (CAS 1310-58-3)

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

BENZOYL PEROXIDE (CAS 94-36-0)

POTASSIUM HYDROXIDE (CAS 1310-58-3)

PROPYLENE GLYCOL (CAS 57-55-6)

US. Pennsylvania Worker and Community Right-to-Know Law

BENZOYL PEROXIDE (CAS 94-36-0)

POTASSIUM HYDROXIDE (CAS 1310-58-3)

PROPYLENE GLYCOL (CAS 57-55-6)

US. Rhode Island RTK

BENZOYL PEROXIDE (CAS 94-36-0)

POTASSIUM HYDROXIDE (CAS 1310-58-3)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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 11-12-2014

Version # 01

Disclaimer

Valeant cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.