



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • ZIANA® (clindamycin phosphate 1.2% and tretinoin 0.025%) Gel
- Product Code** • 399207300304; 399207300601; NDC 99207-0300-30; NDC 99207-0300-60

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

- Recommended use** • Finished Pharmaceutical Product; For the treatment of acne.
- 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** • Skin Mild Irritation 3
Eye Irritation 2

Label elements

UN GHS

WARNING



- Hazard statements** • Causes serious eye irritation
Causes mild skin irritation

Precautionary statements

- Prevention** • Wash thoroughly after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

- Response**
- IF ON SKIN: Wash with plenty of soap and water.
If skin irritation 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 at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°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
Methylparaben	CAS:99-76-3 EINECS:202-785-7	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Propylparaben	CAS:94-13-3 EINECS:202-307-7	< 0.1%	UN GHS: NDA
Edetate disodium	CAS:6381-92-6	< 0.1%	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
Glycerine	CAS:56-81-5 EINECS:200-289-5	10% TO 15%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Polysorbate 80	CAS:9005-65-6	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Tretinoin	CAS:302-79-4 EINECS:206-129-0	0.025%	UN GHS: NDA
Tromethamine	CAS:77-86-1 EINECS:201-064-4	1% TO 5%	UN GHS: Skin Irrit. 2
Citric acid	CAS:77-92-9 EINECS:201-069-1	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Clindamycin phosphate	CAS:24729-96-2 EINECS:246-433-0	1.2%	UN GHS: NDA
Carbomer Homopolymer Type A	CAS:9003-01-4	< 1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	80% TO 90%	UN GHS: not classified

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation**
- 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.
- Skin**
- Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse.
- Eye**
- 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.
- Ingestion**
- If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

- Notes to Physician**
- Systemic absorption of clindamycin has been demonstrated following topical exposure to this product. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical clindamycin.

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

- 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

- Firefighting Procedures**
- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- None known - product is not flammable or combustible.

- Hazardous Combustion Products**
- No data available

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**
- Keep unauthorized personnel away. For bulk material spills: 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. Ventilate closed spaces before entering.

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

- Use only in well ventilated areas (preferably in a chemical fume hood). Do not breathe dusts, vapors or mists. Do not get in eyes, on skin, or on clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

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
Glycerine (56-81-5)	TWAs	Not established	10 mg/m3 TWAEV (mist)	Not established	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)

Exposure Control Notations

ACGIH

- 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

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. Not required during normal clinical use.

Hands

- Wear protective gloves .

Skin/Body

- Wear protective gloves/protective clothing/eye protection/face protection. Not required during normal clinical use.

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

Material Description			
Physical Form	Liquid Gel	Color	Translucent yellow.
Odor	Not relevant	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	4.5 to 6
Specific Gravity/Relative Density	No data available	Water Solubility	No data available
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Burning Rate Test	Not relevant
Flammability (solid, gas)	Not flammable.		
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 humidities.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Protect from light and heat.

Incompatible materials

- This product is generally compatible with other common materials in a medical facility. Acids. Strong oxidizing agents.

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Tretinoin (0.025%)	302-79-4	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 1100 mg/kg; Irritation: Skin-Human • 0.05 % 24 Hour(s) • Mild irritation
Clindamycin phosphate (1.2%)	24729-96-2	Acute Toxicity: Intravenous-Mouse LD50 • 820 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 Mild Irritation 3
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 2

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 sensitization. Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Eye

- Acute (Immediate)** • Causes serious eye 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			
	CAS	IARC	NTP
Butylated hydroxytoluene	128-37-0	Group 3-Not Classifiable	Evidence of Carcinogenicity
Tretinoin	302-79-4	Not Listed	Evidence of Carcinogenicity
Polysorbate 80	9005-65-6	Not Listed	Evidence of Carcinogenicity
Carbomer Homopolymer Type A	9003-01-4	Group 3-Not Classifiable	Not Listed

Reproductive Effects

- There are no adequate and well-controlled studies in humans. Fertility (Segment 1) studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 290 times the amount of clindamycin delivered from the recommended clinical dose for ZIANA Gel, based on a body surface area comparison) revealed no effects on fertility or mating ability.

Other information

- Systemic absorption of clindamycin has been demonstrated following topical use of this product. Rarely, diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of Ziana gel.

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	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	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

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
Tromethamine	77-86-1	Yes	Yes	Yes
Edetate disodium	6381-92-6	Yes	No	No
Methylparaben	99-76-3	Yes	Yes	Yes
Propylparaben	94-13-3	Yes	Yes	Yes
Carbomer Homopolymer Type A	9003-01-4	Yes	No	Yes
Citric acid	77-92-9	Yes	Yes	Yes
Glycerine	56-81-5	Yes	Yes	Yes
Clindamycin phosphate	24729-96-2	No	Yes	No
Tretinoin	302-79-4	Yes	Yes	Yes
Polysorbate 80	9005-65-6	Yes	No	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Tromethamine	77-86-1	D2B
• Butylated hydroxytoluene	128-37-0	Not Listed
• Glycerine	56-81-5	Uncontrolled product according to WHMIS classification criteria
• Citric acid	77-92-9	E (including 40%)
• Edetate disodium	6381-92-6	Uncontrolled product according to WHMIS classification criteria
• Tretinoin	302-79-4	Not Listed
• Clindamycin phosphate	24729-96-2	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Carbomer Homopolymer Type A	9003-01-4	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Tromethamine	77-86-1	Not Listed
• Butylated hydroxytoluene	128-37-0	1 %
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	1 %
• Edetate disodium	6381-92-6	Not Listed
• Tretinoin	302-79-4	Not Listed
• Clindamycin phosphate	24729-96-2	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer Homopolymer Type A	9003-01-4	Not Listed

United States

Environment

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

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Tromethamine	77-86-1	Not Listed
• Butylated hydroxytoluene	128-37-0	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Tretinoin	302-79-4	Not Listed
• Clindamycin phosphate	24729-96-2	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer Homopolymer Type A	9003-01-4	Not Listed

United States - California

Environment

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

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Tromethamine	77-86-1	Not Listed
• Butylated hydroxytoluene	128-37-0	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Tretinoin	302-79-4	Not Listed
• Clindamycin phosphate	24729-96-2	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer Homopolymer Type A	9003-01-4	Not Listed

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

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Tromethamine	77-86-1	Not Listed
• Butylated hydroxytoluene	128-37-0	Not Listed

• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Tretinoin	302-79-4	developmental toxicity, initial date 1/1/89
• Clindamycin phosphate	24729-96-2	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer Homopolymer Type A	9003-01-4	Not Listed

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

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Tromethamine	77-86-1	Not Listed
• Butylated hydroxytoluene	128-37-0	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Tretinoin	302-79-4	Not Listed
• Clindamycin phosphate	24729-96-2	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer Homopolymer Type A	9003-01-4	Not Listed

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

• Methylparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Polysorbate 80	9005-65-6	Not Listed
• Tromethamine	77-86-1	Not Listed
• Butylated hydroxytoluene	128-37-0	Not Listed
• Glycerine	56-81-5	Not Listed
• Citric acid	77-92-9	Not Listed
• Edetate disodium	6381-92-6	Not Listed
• Tretinoin	302-79-4	Not Listed
• Clindamycin phosphate	24729-96-2	Not Listed
• Water	7732-18-5	Not Listed
• Carbomer Homopolymer Type A	9003-01-4	Not Listed

Section 16 - Other Information

- Last Revision Date**
 - 20/April/2015
- Preparation Date**
 - 20/April/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.