



SAFETY DATA SHEET

NFPA Rating: Health: 2

Flammability: 1

Reactivity: 0

Revision Date: 01/07/2020

Date of issue: 01/20/2020

Version: 2.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Veltin (clindamycin phosphate and tretinoin) Gel 1.2% / 0.025%

Synonyms: VELTIN (CLINDAMYCIN PHOSPHATE AND TRETINOIN) GEL, 1.2% / 0.025% * CLINDAMYCIN -TRETINOIN GEL (CLINDAMYCIN 1% - TRETINOIN 0.025%)

1.2. Intended Use of the Product

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

1.3. Name, Address, and Telephone of the Responsible Party

Company

Almirall, LLC
707 Eagleview Blvd
Suite 200
Exton, PA 19341
610-644-7000

Almirall.us

1.4. Emergency Telephone Number

For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident

Call CHEMTREC Day or Night within USA and Canada: 1-800-424-9300 (CCN714268) or +1 703-527-3887 (collect calls accepted)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Skin Sens. 1 H317

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



GHS07

Signal Word (GHS-US)

: Warning

Hazard Statements (GHS-US)

: H317 - May cause an allergic skin reaction.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P363 - Wash contaminated clothing before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Refer to patient insert for more information. Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

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2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%*	GHS-US classification
1,2-Propylene glycol	(CAS No) 57-55-6	Proprietary	Not classified
3,6,9,12-Tetraoxatetracosan-1-ol	(CAS No) 5274-68-0	Proprietary	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo-.alpha.-D-galactooctopyranoside, 2-(dihydrogen phosphate)	(CAS No) 24729-96-2	1	Acute Tox. 4 (Oral), H302 Eye Irrit. 2A, H319 Skin Sens. 1, H317
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	(CAS No) 77-86-1	Proprietary	Not classified
Citric acid	(CAS No) 77-92-9	Proprietary	Comb. Dust, H232 Eye Irrit. 2A, H319
Ethylenediaminetetraacetic acid	(CAS No) 60-00-4	Proprietary	Eye Irrit. 2A, H319 Aquatic Acute 3, H402 Aquatic Chronic 3, H412
2,6-Di-tert-butyl-p-cresol	(CAS No) 128-37-0	Proprietary	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
all-trans-Retinoic acid	(CAS No) 302-79-4	< 0.1	Skin Irrit. 2, H315 Repr. 1B, H360 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

*The specific chemical identity and/or exact percentage of composition have been withheld as a trade secret in accordance with Paragraph 1910.1200 of Title 29 of the Code of Federal Regulations.

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

First-aid Measures After Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: May cause and allergic skin reaction. Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed.

Symptoms/Injuries After Inhalation: None expected under normal conditions of use.

Symptoms/Injuries After Skin Contact: May cause and allergic skin reaction.

Symptoms/Injuries After Eye Contact: Direct contact with the eyes is likely irritating.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

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Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Contact competent authorities after a spill.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Keep away from heat and open flame.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use.

Incompatible Products: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL) NIOSH (REL), or OSHA (PEL).

1,2-Propylene glycol (57-55-6)		
USA AIHA	WEEL TWA (mg/m ³)	10 mg/m ³
2,6-Di-tert-butyl-p-cresol (128-37-0)		
USA ACGIH	ACGIH TWA (mg/m ³)	2 mg/m ³ (inhalable fraction and vapor)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10 mg/m ³

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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Personal Protective Equipment : Gloves. Safety glasses.



Hand Protection : Protective Gloves.

Eye Protection : Safety glasses.

Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Yellow Gel
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions are unlikely to occur under normal circumstances.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible Materials:

Strong oxidizers.

10.6. Hazardous Decomposition Products:

Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

1,2-Propylene glycol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg
Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo-.alpha.-D-galacto-octopyranoside, 2-(dihydrogen phosphate) (24729-96-2)	
LD50 Oral Rat	1832 mg/kg

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1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rat	> 5000 mg/kg
Citric acid (77-92-9)	
LD50 Oral Rat	5400 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
Ethylenediaminetetraacetic acid (60-00-4)	
LD50 Oral Rat	> 2000 mg/kg
2,6-Di-tert-butyl-p-cresol (128-37-0)	
LD50 Oral Rat	> 2930 mg/kg (Species: Sprague-Dawley)
LD50 Dermal Rat	> 2000 mg/kg
all-trans-Retinoic acid (302-79-4)	
LD50 Oral Rat	2 g/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

2,6-Di-tert-butyl-p-cresol (128-37-0)	
IARC group	3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Overexposure may be irritating to the respiratory system.

Symptoms/Injuries After Skin Contact: None expected under normal conditions of use.

Symptoms/Injuries After Eye Contact: Direct contact with the eyes is likely irritating.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

1,2-Propylene glycol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC 50 Fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
Citric acid (77-92-9)	
LC50 Fish 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
Ethylenediaminetetraacetic acid (60-00-4)	
LC50 Fish 1	34 - 62 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 1	113 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC 50 Fish 2	44.2 - 76.5 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
NOEC chronic fish	>= 25.7 mg/l (Duration: 35 d - Species: Brachydanio rerio [Flow-through])
NOEC chronic crustacea	25 mg/l (Duration: 21 d - Species: Daphnia magna [Semi-static])
2,6-Di-tert-butyl-p-cresol (128-37-0)	
EC50 Other Aquatic Organisms 2	0.43 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)

12.2. Persistence and Degradability

Veltin (clindamycin phosphate and tretinoin) Gel 1.2% / 0.025%	
Persistence and Degradability	Not established.
Citric acid (77-92-9)	
Persistence and Degradability	Readily biodegradable in water.

12.3. Bioaccumulative Potential

Veltin (clindamycin phosphate and tretinoin) Gel 1.2% / 0.025%	
Bioaccumulative Potential	Not established.

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1,2-Propylene glycol (57-55-6)	
BCF fish 1	< 1
Log Pow	-0.92
Citric acid (77-92-9)	
Log Pow	-1.72 (at 20 °C)
2,6-Di-tert-butyl-p-cresol (128-37-0)	
BCF fish 1	230 - 2500
Log Pow	4.17

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

1,2-Propylene glycol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule
3,6,9,12-Tetraoxatetracosan-1-ol (5274-68-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Citric acid (77-92-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Ethylenediaminetetraacetic acid (60-00-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
2,6-Di-tert-butyl-p-cresol (128-37-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
all-trans-Retinoic acid (302-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2 US State Regulations

all-trans-Retinoic acid (302-79-4)	
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.
1,2-Propylene glycol (57-55-6)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	

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Ethylenediaminetetraacetic acid (60-00-4)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

U.S. - Pennsylvania - RTK (Right to Know) List

2,6-Di-tert-butyl-p-cresol (128-37-0)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date	: 09/01/2018 Updated Company Name 01/20/2020 Updated Company Address
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 1B	Reproductive toxicity Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H360	May damage fertility or the unborn child
H400	Very toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)