Safety Data Sheet



Section 1: Identification

Product identifier

Product Name

Erythromycin-Benzoyl Peroxide Topical Gel

Product Code

 NDC 68682-900-23; NDC 68682-901-46; NDC 68682-922-46 Benzoyl peroxide gel; NDC 68682-923-23 Benzoyl peroxide gel; NDC 68682-924-08 Erythromycin; NDC 68682-925-16 Erythromycin

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

Recommended use

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

2150 St. Elzear West Laval H7L 4A8

Canada 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

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 Sensitization 1 Skin Irritation 2 Eve Irritation 2A

Label elements

UN GHS

WARNING



Hazard statements • Causes serious eye irritation Causes skin irritation

May cause an allergic skin reaction

Precautionary statements

Preparation Date: 26/March/2015 Format: GHS Language: English (US) **UN GHS** Revision Date: 26/March/2015 Page 1 of 11

Prevention • Wash thoroughly after handling.

Wear eye/face protection - safety glasses, face shield.

Wear protective gloves.

Response • 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 (and not prescribed): Wash with plenty of soap and water.

If skin irritation occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

Storage/Disposal • Keep tightly closed. Prior to reconstitution, store at room temperature 15-30°C (59-86°F), to maintain product integrity. After reconstitution, store refrigerated 2-8°C (36-46°F). Do not freeze. Use before expiration 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 | |
| Erythromycin | CAS:114-07-8 EINECS:204-040-1 | 3% | UN GHS: Skin Irrit. 2; Eye Irrit. 2A | |
| Benzoyl peroxide gel vehicle | | N/A | UN GHS: NDA | |
| Carbomer homopolymer 980 [1.5%] | CAS:9003-01-4 | 1% TO 5% | UN GHS: not classified | |
| Sodium hydroxide [0.4095%] | CAS:1310-73-2 EINECS:215-185-5 | < 1% | UN GHS: Skin Corr. 1A | |
| Ethanol [15%] | CAS:64-17-5 EINECS:200-578-6 | 10% TO 20% | UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Muta. 1B; Repr. 1B | |
| Methyl salicylate [0.05%] | CAS:119-36-8 EINECS:204-317-7 | < 0.1% | UN GHS: not classified | |
| Dioctyl sodium sulfouccinate [0.2%] | CAS:577-11-7 EINECS:209-406-4 | < 1% | UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 4 | |
| Water [74.078%] | CAS:7732-18-5 EINECS:231-791-2 | 70% TO 80% | UN GHS: not classified | |
| Benzoyl peroxide [8.7125%] | CAS:94-36-0 EINECS:202-327-6 | 5% | UN GHS: Skin Corr. 1; Eye Dam. 1; Eye Irrit. 2A; Skin Sens. 1 | |
| Lemon fragrance oil [0.05%] | NDA | < 0.1% | UN GHS: NDA | |

This medication must be reconstituted. Prior to dispensing, add indicated amount of room temperature 70% ethyl alcohol to the vial and immediately shake to completely dissolve erythromycin. Add this solution to gel and stir until homogeneous in appearance (1 to 1½ minutes).

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

Preparation Date: 26/March/2015 Format: GHS Language: English (US) Revision Date: 26/March/2015 **UN GHS** Page 2 of 11

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

 No adverse effects anticipated by breathing small amounts. If large amounts are inhaled, remove to fresh air.

Skin

IF ON SKIN (and not prescribed): Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

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, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Carbon dioxide, dry chemical powder, appropriate foam or water fog.

Unsuitable Extinguishing Media

No data available

Firefighting Procedures

As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion

Hazards

No data available

Hazardous Combustion

Products

No data available

Advice for firefighters

No data available

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

Ventilate area. 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. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Dispose of in accordance with Section 13.

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

No data available

Preparation Date: 26/March/2015 Format: GHS Language: English (US) Revision Date: 26/March/2015 **UN GHS** Page 3 of 11

Section 7 - Handling and Storage

Precautions for safe handling

Handling

 Avoid contact with eyes. Avoid prolonged or repeated exposure to skin or mucous membranes, and breathing mists/vapors. Use in a well ventilated area, away from all sources of ignition. Keep container closed. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities

Storage

 Keep tightly closed. Prior to reconstitution, store at room temperature 15-30°C (59-86°F), to maintain product integrity. After reconstitution, store refrigerated 2-8°C (36-46°F). Do not freeze. Use before expiration date marked on carton and/or container.

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 | | | | | |
| Sodium hydroxide | Ceilings | 2 mg/m3 Ceiling | 2 mg/m3 Ceiling | 2 mg/m3 Ceiling | Not established | |
| (1310-73-2) | TWAs | Not established | Not established | Not established | 2 mg/m3 TWA | |
| Benzoyl peroxide (94-36-0) | TWAs | 5 mg/m3 TWA | 5 mg/m3 TWAEV | 5 mg/m3 TWA | 5 mg/m3 TWA | |
| Ethanol | TWAs | Not established | 1000 ppm TWAEV; 1880 mg/m3 TWAEV | 1000 ppm TWA; 1900 mg/m3 TWA | 1000 ppm TWA; 1900 mg/m3 TWA | |
| (64-17-5) | 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)
- •Benzoyl peroxide (94-36-0): Carcinogens: (A4 Not Classifiable as a Human Carcinogen)

Exposure controls

Engineering Measures/Controls

Pictograms

• No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

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 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 Hands

Wear eye/face protection, .

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.

Preparation Date: 26/March/2015 Revision Date: 26/March/2015

General Industrial Hygiene Considerations

Environmental Exposure Controls

- Handle in accordance with good industrial hygiene and safety practice.
- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

| Material Description | | | | |
|-------------------------------------|---------------|----------------|--------------|--|
| Physical Form | Liquid Gel | Color | Not relevant | |
| Odor | Not relevant | Odor Threshold | Not relevant | |
| General Properties | | | - | |
| Boiling Point | Not relevant | Melting Point | Not relevant | |
| Decomposition Temperature | Not relevant | pH | Not relevant | |
| Specific Gravity/Relative Density | Not relevant | Density | Not relevant | |
| Water Solubility | Not relevant | Viscosity | Not relevant | |
| Volatility | | - | - | |
| Vapor Pressure | Not relevant | Vapor Density | Not relevant | |
| Evaporation Rate | Not relevant | | | |
| Flammability | | - | | |
| Flash Point | Not relevant | UEL | Not relevant | |
| LEL | Not relevant | Flame Duration | Not relevant | |
| Flame Extension | Not relevant | Autoignition | Not relevant | |
| Flammability (solid, gas) | Not relevant | | | |
| Environmental | | | | |
| Octanol/Water Partition coefficient | Not relevant | | | |

Section 10: Stability and Reactivity

Reactivity

Stable under normal temperatures and pressures.

Chemical stability

• Stable when stored at room temperature 15-25°C (59-77°F). Use before expiration date marked on carton and/or container. Prior to reconstitution, stable when stored at room temperature 15-30°C (59-86°F). After reconstitution, store refrigerated at 2-8°C (36-46°F). Use before expiration date marked on carton and/or container.

Possibility of hazardous reactions

No data available

Conditions to avoid

No data available

Incompatible materials

Light, strong oxidizers, alkalis.

Hazardous decomposition products

No data available

Section 11 - Toxicological Information

Preparation Date: 26/March/2015 Format: GHS Language: English (US) Revision Date: 26/March/2015 **UN GHS** Page 5 of 11

Information on toxicological effects

| | | Components |
|---|---------------|--|
| Erythromycin (3%) | 114- 07-8 | Acute Toxicity: Ingestion/Oral-Rat LD50 • 4600 mg/kg |
| Carbomer homopolymer 980 (1% TO 5%) | 9003- 01-4 | Acute Toxicity: Ingestion/Oral-Rat LD50 • 2500 mg/kg |
| Sodium hydroxide (< 1%) | 1310- 73-2 | Acute Toxicity: Intraperitoneal-Mouse LD50 • 40 mg/kg; Irritation: Eye-Rabbit • 1 mg 30 Second(s)-Rinse • Severe irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Severe irritation |
| Ethanol (10% TO 20%) | 64-17- 5 | Acute Toxicity: Ingestion/Oral-Rat LD50 • 7060 mg/kg; Lungs, Thorax, or Respiration:Other changes; Irritation: Eye-Rabbit • 500 mg • Severe irritation; Skin-Rabbit • 20 mg 24 Hour(s) • Moderate irritation; Mutagen: Dominant lethal test • Ingestion/Oral-Mouse • 3720 mg/kg 3 Day(s); DNA damage • Ingestion/Oral-Rat • 4 g/kg; Reproductive: Ingestion/Oral-Rat TDLo • 147 mg/kg (1-21D preg); Reproductive Effects:Specific Developmental Abnormalities:Endocrine system; Reproductive Effects:Effects on Newborn:Delayed effects; Ingestion/Oral-Rat TDLo • 90 mg/kg (30D male); Reproductive Effects:Paternal Effects:Spermatogenesis; Reproductive Effects:Paternal Effects:Paternal Effects on Fertility:Male fertility index; Tumorigen / Carcinogen: Ingestion/Oral-Mouse TDLo • 320 mg/kg 50 Week(s)-Intermittent; Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Liver:Tumors; Blood:Lymphoma, including Hodgkin's disease |
| Methyl salicylate (< 0.1%) | 119- 36-8 | Acute Toxicity: Ingestion/Oral-Mouse LD50 • 1110 mg/kg; Ingestion/Oral-Rat LD50 • 887 mg/kg; Behavioral:Somnolence (general depressed activity); Irritation: Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Moderate irritation |
| Dioctyl sodium sulfouccinate (< 1%) | 577- 11-7 | Acute Toxicity: Ingestion/Oral-Rat LD50 • 1900 mg/kg; Irritation: Eye-Rabbit • 250 μg • Mild irritation; Skin-Rabbit • 10 mg 24 Hour(s) • Moderate irritation |
| Benzoyl peroxide (5%) | 94-36- 0 | Acute Toxicity: Ingestion/Oral-Rat LD50 • 6400 mg/kg; Irritation: Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Skin-Human • 5 % 8 Week(s)-Intermittent • Severe irritation |

| 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 • Skin Sensitizer 1 |
| 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.

Preparation Date: 26/March/2015 Revision Date: 26/March/2015 **Chronic (Delayed)**

No data available

Skin

Acute (Immediate)

 Causes irritation of the skin including dryness, peeling, itching, burning sensation, erythema, inflammation.

Chronic (Delayed)

Repeated and prolonged exposure may cause sensitization.

Eye

Acute (Immediate)

Causes serious eye irritation.

Chronic (Delayed)

Repeated and prolonged exposure may be harmful.

Ingestion

Acute (Immediate)

. May be harmful.

Chronic (Delayed)

No data available

Carcinogenic Effects

 Data from a study using mice known to be highly susceptible to cancer suggests that benzoyl peroxide acts as a tumor promoter. The clinical significance of this is unknown. No animal studies have been performed to evaluate the carcinogenic and mutagenic potential or effects on fertility of topical erythromycin. However, long-term (2-year) oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity.

| Carcinogenic Effects | | | | |
|--------------------------|-----------|--------------------------|-----------------------------|--|
| CAS IARC NTP | | | | |
| Carbomer homopolymer 980 | 9003-01-4 | Group 3-Not Classifiable | Not Listed | |
| Ethanol | 64-17-5 | Group 1-Carcinogenic | Evidence of Carcinogenicity | |
| Benzoyl peroxide | 94-36-0 | Group 3-Not Classifiable | Not Listed | |

Reproductive Effects

 There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% diet) prior to and during mating, during gestation and through weaning of two successive litters. There are no well-controlled trials in pregnant women with Erythromycin-Benzoyl Peroxide Topical 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

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

Packaging waste

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

Preparation Date: 26/March/2015

Revision Date: 26/March/2015

Page 7 of 11

Format: GHS Language: English (US)

UN GHS

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 | Canada NDSL | EU EINECS | TSCA |
| Benzoyl peroxide | 94-36-0 | Yes | No | Yes | Yes |
| Dioctyl sodium sulfouccinate | 577-11-7 | Yes | No | Yes | Yes |
| Carbomer homopolymer 980 | 9003-01-4 | Yes | No | No | Yes |
| Erythromycin | 114-07-8 | Yes | No | Yes | No |
| Ethanol | 64-17-5 | Yes | No | Yes | Yes |
| Methyl salicylate | 119-36-8 | Yes | No | Yes | Yes |
| Sodium hydroxide | 1310-73-2 | Yes | No | Yes | Yes |
| Water | 7732-18-5 | Yes | No | Yes | Yes |

Canada

| Labor | | |
|--|-----------|---|
| Canada - WHMIS - Classifications of Substances | | |
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | D2A |
| Benzoyl peroxide | 94-36-0 | C, D2B, F; C, D2B (70%) |
| Sodium hydroxide | 1310-73-2 | E (including 0.04% in aqueous solution, 0.08%, 0.4% in aqueous solution, 2%, 2.5%, 4% in aqueous solution, 5%, 10%, 16%, 20%, 40%, 50% in aqueous solution, 8.7N) |
| • Ethanol | 64-17-5 | B2, D2B |
| • Water | 7732-18-5 | Uncontrolled product according to WHMIS classification criteria |

Preparation Date: 26/March/2015 Revision Date: 26/March/2015

| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
|---|-----------|------------|
| Canada - WHMIS - Ingredient Disclosure List | | |
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | 1 % |
| Methyl salicylate | 119-36-8 | 0.1 % |
| Benzoyl peroxide | 94-36-0 | 1 % |
| Sodium hydroxide | 1310-73-2 | 1 % |
| • Ethanol | 64-17-5 | 0.1 % |
| Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| | | |

Europe

| ther | | |
|--|-----------|---|
| EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification | | |
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | E; R3 Xi; R36 R43 O; R7 |
| Sodium hydroxide | 1310-73-2 | C; R35 |
| • Ethanol | 64-17-5 | F; R11 |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| EU - CLP (1272/2008) - Annex VI - Table 3.2 - Concentration Limits | | |
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | Not Listed |
| | | 5%<=C: C; R:35 2%<=C<5% |
| Sodium hydroxide | 1310-73-2 | C; R:34 0.5%<=C<2%: Xi; R:36/38 |
| • Ethanol | 64-17-5 | Not Listed |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling | | |
| • Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | E Xi R:3-7-36-43 S:(2)-3/7-14 36/37/39 |
| Sodium hydroxide | 1310-73-2 | C R:35 S:(1/2)-26-37/39-45 |
| • Ethanol | 64-17-5 | F R:11 S:(2)-7-16 |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases | | |
| • Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | S:(2)-3/7-14-36/37/39 |
| Sodium hydroxide | 1310-73-2 | S:(1/2)-26-37/39-45 |
| • Ethanol | 64-17-5 | S:(2)-7-16 |

Preparation Date: 26/March/2015 Revision Date: 26/March/2015 Format: GHS Language: English (US)

| • V | Vater | 7732-18-5 | Not Listed |
|-----|--------------------------|-----------|------------|
| • C | Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| | | | |

United States

| J.S OSHA - Process Safety Management - Highly Hazardous Chemicals | 5 | |
|---|-----------|------------|
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | 7500 lb TQ |
| Sodium hydroxide | 1310-73-2 | Not Listed |
| • Ethanol | 64-17-5 | Not Listed |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |

| nvironment U.S CERCLA/SARA - Hazardous Substances and their Reportable Quantities | | |
|---|-----------|-----------------------------------|
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | Not Listed |
| Sodium hydroxide | 1310-73-2 | 1000 lb final RQ; 454 kg final RQ |
| • Ethanol | 64-17-5 | Not Listed |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| U.S CERCLA/SARA - Section 313 - Emission Reporting | | |
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | 1.0 % de minimis concentration |
| Sodium hydroxide | 1310-73-2 | Not Listed |
| • Ethanol | 64-17-5 | Not Listed |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |

United States - California

| Environment U.S California - Proposition 65 - Carcinogens List | | |
|--|-----------|---|
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | Not Listed |
| Sodium hydroxide | 1310-73-2 | Not Listed |
| • Ethanol | 64-17-5 | carcinogen, initial date 4/29/11 (in alcoholic beverages) |
| Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| U.S California - Proposition 65 - Developmental Toxicity | | |
| Erythromycin | 114-07-8 | Not Listed |

Preparation Date: 26/March/2015 Revision Date: 26/March/2015

Format: GHS Language: English (US)

| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
|--|-----------|---|
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | Not Listed |
| Sodium hydroxide | 1310-73-2 | Not Listed |
| • Ethanol | 64-17-5 | developmental toxicity, initial date 10/1/87 (in alcoholic beverages) |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| U.S California - Proposition 65 - Reproductive Toxicity - Female | | |
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | Not Listed |
| Sodium hydroxide | 1310-73-2 | Not Listed |
| Ethanol | 64-17-5 | Not Listed |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |
| U.S California - Proposition 65 - Reproductive Toxicity - Male | | |
| Erythromycin | 114-07-8 | Not Listed |
| Dioctyl sodium sulfouccinate | 577-11-7 | Not Listed |
| Methyl salicylate | 119-36-8 | Not Listed |
| Benzoyl peroxide | 94-36-0 | Not Listed |
| Sodium hydroxide | 1310-73-2 | Not Listed |
| • Ethanol | 64-17-5 | Not Listed |
| • Water | 7732-18-5 | Not Listed |
| Carbomer homopolymer 980 | 9003-01-4 | Not Listed |

Section 16 - Other Information

Last Revision Date Preparation Date Disclaimer/Statement of Liability

- 26/March/2015
- 26/March/2015
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