SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Benzoyl Peroxide Aqueous Base Gel 2.5%, 5%, 10%
Synonym: 265, 503, 339

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Treatment of acne
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Skin Sensitizer Category 1 Eye Irritant Category 2A

Label Elements:
Warning!



Hazard statement(s)

Causes serious eye irritation.
May cause an allergic skin reaction.

Precautionary statement(s)
Wash hands thoroughly after handling
Avoid breathing vapors or mists.
Wear protective gloves.

Precautionary statement(s)

Contaminated clothing must not be allowed out of the workplace.
IF on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention.
Wash contaminated clothing before reuse.
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 attention.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Benzoyl Peroxide	94-36-0	2.5-10%
Glycerin	56-81-5	Proprietary
Carbomer Homopolymer	9003-01-4	Proprietary
Dimethicone	9006-65-9	Proprietary
Methyl Paraben	99-76-3	Proprietary
Sodium Hydroxide	1310-73-2	<=0.5%
Water	7732-18-5	Proprietary
Silicon Dioxide	7631-86-9	Proprietary
Poloxamer 182	9003-11-6	Proprietary
Edetate Disodium Dihydrate	6381-92-6	Proprietary
Disodium Lauryl Sulfosuccinate	19040-44-9	Proprietary

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact: This product is intended for use on the skin. If irritation develops and persists, discontinue use and get medical attention. Remove and contaminated clothing and launder it before reuse.
Eye contact: Immediately flush eyes with water for 15 minutes while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

Most important symptoms/effects, acute and delayed: Causes eye irritation. May cause skin irritation. Ingestion may cause gastrointestinal distress. May cause an allergic skin reaction.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention may be required for large ingestions.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but may burn in a fire after the water has evaporated.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and **c**ollect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Benzoyl Peroxide	5 mg/m3 TWA ACGIH TLV 5 mg/m3 TWA OSHA PEL
Glycerin	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Carbomer Homopolymer	None Established
Dimethicone	None Established
Methyl Paraben	None Established
Sodium Hydroxide	2 mg/m3 Ceiling ACGIH TLV 2 mg/m3 TWA OSHA PEL
Water	None Established
Silicon Dioxide	80 mg/m3 / % SiO2
Poloxamer 182	None Established
Edetate Disodium Dihydrate	None Established
Disodium Lauryl Sulfosuccinate	None Established

Appropriate engineering controls: No special ventilation required for normal use. Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: This product is intended for use on the skin. Impervious gloves recommended for handling this product other than for use.
Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White to off-white gel.
Odor: Odorless

Odor threshold: Not applicable	**pH:** Not determined
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: None	**Evaporation rate:** Same as water
Flammability (solid, gas): Not applicable	**VOC:** Not determined
Flammable limits: LEL: None	**UEL:** None
Vapor pressure: Same as water	**Vapor density:** Same as water
Relative density: Not determined	**Solubility(ies):** Soluble in water
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: Avoid excessive heat.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.
Ingestion: Swallowing may cause gastrointestinal distress with nausea and diarrhea.
Skin contact: No adverse effects are expected. Some users have reported skin burning and irritation.
Eye contact: Contact may cause irritation with redness and tearing.
Chronic Effects: None known.
Sensitization: Benzoyl peroxide is a skin sensitizer.
Germ Cell Mutagenicity: No adverse effects are expected. Components are not germ cell mutagens. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *Salmonella typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells.
Reproductive Toxicity: Components are not reproductive toxins.
Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA. Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced squamous cell skin tumors in transgenic TgAC mice in a study using 20 weeks of topical treatment. The clinical significance of this is unknown.

Acute Toxicity Values:
Benzoyl peroxide: LD50 oral rat >5000 mg/kg; LC50 inhalation rat >24.3 mg/L/4 hr (no mortality)
Glycerin: LD50 oral rat 12.6 g/kg

12. ECOLOGICAL INFORMATION

Very toxic to aquatic organisms.

Ecotoxicity values: Benzoyl peroxide: LC50 Oncorhynchus mykiss 0.0316 mg/L/96 hr; EC50 daphnia magna 0.0602 mg/L/48 hr; ErC50 Pseudokirchnerella subcapitata 0.0711 mg/L/72 hr.
Persistence and degradability: Benzoyl peroxide is readily biodegradable
Bioaccumulative potential: Benzoyl peroxide has a log Kow of 3.2. The potential for bioaccumulation is low.
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG	UN3082	Environmentally Hazardous Substance, liquid, n.o.s. (benzoyl peroxide 10%)	9	III	Marine Pollutant
IATA	UN3082	Environmentally Hazardous Substance, liquid, n.o.s. (benzoyl peroxide 10%)	9	III	Yes

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Acute Health
EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
Benzoyl Peroxide 94-36-0 2.5-10%

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**
CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.
Canadian WHMIS Classification: Drugs are exempt from WHMIS
This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 0 Instability = 0

HMIS Rating: Health = 1 Flammability = 0 Physical Hazard = 0

SDS Revision History: Correct classification (Section 2)
Date of preparation: May 10, 2015

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).