



SAFETY DATA SHEET

Simethicone Drops (40mg/0.6mL)

SDS DATE: 28-Sep-2015

SECTION 1: IDENTIFICATION

PRODUCT NAME: Simethicone Drops (40mg/0.6mL)
SYNONYMS: Poly(dimethylsiloxane), silicon dioxide
NDC Number: 46287-506-30
MANUFACTURER: CMP Pharma, Inc.
ADDRESS: PO Box 147
8026 US Hwy. 264A
Farmville, NC 27828

EMERGENCY PHONE: 1-800-227-6637
CHEMTREC PHONE: 1-908-859-2151
OTHER CALLS: 1-252-753-7111

CHEMICAL NAME (for active ingredient): Poly(dimethylsiloxane), silicon dioxide
CHEMICAL FAMILY (for active ingredient): Anti-foaming Agent
CHEMICAL FORMULA (for active ingredient): $(C_2H_6OSi)_n \cdot (SiO_2)_m$

PRODUCT USE: Anti-flatulent

SECTION 2: HAZARD(S) IDENTIFICATION

PHYSICAL HAZARDS: None known.
HEALTH HAZARDS: None known.
HAZARD SYMBOLS: Not a hazardous substance or mixture.
HAZARDS NOT OTHERWISE CLASSIFIED: None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| INGREDIENT: | CAS NO. | Amount |
|-------------------------------|----------------|---------------|
| Simethicone Emulsion USP, 30% | 8050-81-5 | >99% |
| Potassium Sorbate | 590-00-1 | < 1% |

SECTION 4: FIRST AID MEASURES

EYE CONTACT: Flush with copious amounts of water for at least 15 minutes. Seek medical attention if symptoms persist.
SKIN CONTACT: Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.
INGESTION: Do not induce vomiting. Toxicity is low after acute ingestion. Seek medical attention if symptoms persist.
INHALATION: If breathing is difficult, remove to fresh air. Seek medical attention if symptoms persist.

MOST IMPORTANT SYMPTOMS/EFFECTS

ACUTE OR DELAYED:
None known.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

Treat any symptoms and eliminate exposure.



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SECTION 5: FIRE-FIGHTING MEASURES

| | |
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| SUITABLE EXTINGUISHING MEDIA: | Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials. |
| UNSUITABLE EXTINGUISHING MEDIA: | None known. |
| UNUSUAL FIRE AND EXPLOSION HAZARDS: | Exposure to combustion products may be hazardous to health. |
| HAZARDOUS COMBUSTION PRODUCTS: | Silicon oxides, carbon oxides, formaldehyde. |
| SPECIAL FIRE FIGHTING PROCEDURES: | Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment. |

SECTION 6: ACCIDENTAL RELEASE MEASURES

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| PERSONAL PRECAUTIONS: | Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Discharge into the environment should be avoided. Retain and appropriately dispose of all contaminated wash water. |
| METHODS/MATERIALS USED FOR CONTAINMENT & CLEANING: | Collect spillage with inert absorbent material. Dampen remaining residue with water, then clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance. |

SECTION 7: HANDLING AND STORAGE

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| HANDLING PRECAUTIONS: | Clean equipment and work surfaces with suitable detergent or solvent after use. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts, shoes, and any other items that cannot be decontaminated. |
| STORAGE PRECAUTIONS: | When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. Keep this drug out of the reach of children. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

| Component Name | WEEL (TWA) | OSHA PEL (TWA) | ACGIH TLV (TWA) | HSE WEL (TWA) |
|-------------------------------|------------|----------------------|----------------------|---------------|
| Simethicone Emulsion USP, 30% | N/A | 80 mg/m ³ | 10 mg/m ³ | N/A |
| Potassium Sorbate | N/A | N/A | N/A | N/A |

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| ENGINEERING CONTROLS: | In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit. |
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PERSONAL PROTECTIVE EQUIPMENT (PPE)

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| EYE PROTECTION: | Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur. |
| SKIN PROTECTION: | Avoid unintended skin contact. Wear gloves impervious to conditions of use. A safety shower should be located in the work area. |
| RESPIRATORY PROTECTION: | If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection. |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ODOR: This product is a white to off-white liquid with no discernible odor.

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| FLASH POINT: | > 101.1°C | % VOLATILE: | Not established. |
| AUTOIGNITION TEMP: | Not established. | VISCOSITY: | Not established. |
| BOILING POINT: | > 90°C | pH: | Not established. |
| MELTING POINT: | Not established. | Octanol/H₂O PART. COEFFICIENT: | Not established. |
| VAPOR PRESSURE (mmHg): | Not established. | POUR POINT: | Not established. |
| EVAPORATION RATE (H₂O = 1): | Not established. | % SOLUBILITY IN WATER: | Not established. |
| VAPOR DENSITY (AIR = 1): | 1.0 | SPECIFIC GRAVITY (H₂O = 1): | Not established. |
| LOWER FLAMMABILITY LIMIT: | Not established. | UPPER FLAMMABILITY LIMIT: | Not established. |

SECTION 10: STABILITY AND REACTIVITY

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| REACTIVITY: | No reactivity hazards known. |
| CHEMICAL STABILITY: | Material is stable under normal conditions. |
| POSSIBILITY OF HAZARDOUS REACTIONS: | Use at elevated temperatures may form highly hazardous compounds. |
| CONDITIONS TO AVOID: | None known. |
| INCOMPATIBLE MATERIALS: | Strong oxidizing agents should be avoided. |
| HAZARDOUS DECOMPOSITION PRODUCTS: | Formaldehyde |

SECTION 11: TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE:

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| INGESTION: | No acute oral toxicity. |
| INHALATION: | Although unlikely due to product form, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon exposure to fresh air. |
| SKIN CONTACT: | No acute dermal toxicity. |
| EYE CONTACT: | Avoid contact with eyes. May cause irritation of the eyes. |

SIGNS AND SYMPTOMS OF OVEREXPOSURE:

Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

CHRONIC EFFECTS:

None classified.

ACUTE TOXICITY VALUES: LD 50 for Simethicone Emulsion USP, 30% (oral, rat) = 5 g/kg



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SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

WASTE DISPOSAL CONTAINERS:

Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TOXIC SUBSTANCE CONTROL ACT (TSCA):

All components of this product are included on the TSCA inventory.

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):

There are no ingredients in this mixture listed under SARA.

STATE REGULATIONS:

WARNING! This product contains a chemical known to the State of California to cause cancer (sulphuric acid).

INTERNATIONAL REGULATIONS:

EU RISK (R) AND SAFETY (S) PHRASES (OCCUPATIONAL EXPOSURE):

S2 Keep out of the reach of children
S36/27 Wear suitable protective clothing and gloves

SECTION 16: OTHER INFORMATION

NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) RATINGS:

Health: 0 Flammability: 1 Reactivity: 0 Other: 0

CREATION DATE:

28Sep2015

REVISION DATE:

N/A

DISCLAIMER:

CMP Pharma, Inc. believes that the information contained in this Safety Data Sheet (SDS) is accurate, and while it is provided in good faith, it is without warranty of any kind, express or implied.

The information contained herein is designated only as guidance for safe handling and storage of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment, should handle all chemicals. CMP Pharma, Inc. shall not be held liable for any loss, injury, or damage from contact with the product.