



SAFETY DATA SHEET

Simethicone Drops for Gas Relief

1. IDENTIFICATION

Product identifier: Simethicone Drops for Gas Relief 20mg/0.3mL and 40mg/0.6mL Oral Prefilled Liquid Syringe

Product Codes:

- 0121-1094-03 (20mg/0.3mL)
- 0121-1095-03 (40mg/0.6mL)

Supplier Name and Address: PAI Pharma
1700 Perimeter Road
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – gas relief

Restrictions on use: Use only as directed

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Label Elements:

Not hazardous in accordance with the GHS and OSHA Hazcom 2024.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Simethicone	8050-81-5	<1%
Citric Acid	77-92-9	<10%
Carboxymethyl cellulose	9032-42-2	Proprietary
Microcrystalline cellulose	9004-34-6	Proprietary
Flavors	Mixture	Proprietary
Polysorbate 20	9005-64-5	Proprietary
Potassium sorbate	24634-61-5	Proprietary
Sodium benzoate	532-32-1	Proprietary
Sorbitan Monostearate	1338-41-6	Proprietary
Sorbitol	50-70-4	Proprietary
Xanthan gum	11138-66-2	Proprietary
Water	7732-18-5	Proprietary

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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 or other symptoms occur, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdosage, rinse mouth with water. Get medical attention if any symptoms develop.

Most important symptoms/effects, acute and delayed: May cause minor eye irritation. May cause mild skin irritation.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not generally required.

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 classified as flammable or combustible but will 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.

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 collect 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.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Simethicone	None Established
Citric Acid	None Established
Carboxymethyl cellulose	None Established
Microcrystalline cellulose	5 mg/m ³ (respirable), 15 mg/m ³ (total) OSHA PEL 10 mg/m TWA ACGIH TLV
Flavors	None Established
Polysorbate 20	None Established
Potassium sorbate	None Established
Sodium benzoate	2.5 mg/m ³ (inhalable) TWA skin ACGIH TLV
Sorbitan Monostearate	None Established
Sorbitol	None Established
Xanthan gum	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, 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: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid	pH: 5
Odor: No specific odor	Color: Colorless to slightly colored
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	Particle Characteristics: Not applicable for liquids
Flammability: Not flammable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapor pressure: Same as water	Relative vapor density: Same as water
Relative density: 1.05	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available

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Decomposition temperature: Not available

Kinematic 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: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.

Ingestion: No adverse effects are expected.

Skin contact: May cause mild irritation.

Eye contact: May cause mild irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens

Reproductive Toxicity: Components are not classified as reproductive toxins.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: Simethicone: EC50 daphnia magna 245 mg/L/48h; LC50 Lepomis macrochirus >10,000 mg/L/96h

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

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.

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14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk according to IMO instruments: 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): Refer to Section 2 for the OSHA hazard classification.

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain listed chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: New SDS

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality

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specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.