



SAFETY DATA SHEET

SUPREP® BOWEL PREP KIT

(sodium sulfate, potassium sulfate and magnesium sulfate)

Oral Solution

A Prescription Drug Product

Section 1. Product and Company Identification

Product Name	SUPREP® BOWEL PREP KIT
Manufacturer	Braintree Laboratories, Inc.
Address	P.O. Box 850929 60 Columbian Street Braintree, MA 02185-0929
Phone Number	(781) 843-2202
Emergency Phone Number	(781) 843-2202
Recommended Use	Prescription Drug Product
Restrictions on Use	Use only with a licensed practitioner's prescription

Section 2. Hazard(s)

Inhalation:

No adverse effects are anticipated by this route of exposure incidental to proper handling.
Not expected to require first aid measures. Get medical attention for any breathing difficulties.

Skin:

May be a slight irritant on sensitive skin. Wash with soap and water.

Eyes:

Flush with running water for 15 minutes holding eyelids open, seek medical attention.

Ingestion:

Product is an osmotic laxative and will produce diarrhea. No adverse effects are anticipated by this route of exposure incidental to proper handling. If large amounts of concentrated solution were ingested get medical attention. Water should be given in copious amounts to prevent dehydration. Rinse mouth out with large amounts of water, seek medical attention.

Section 3. Composition/Information on ingredients

SUPREP® BOWEL PREP KIT

Each Kit contains: Two 6-ounce bottles of SUPREP® (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution. Each SUPREP Bowel Prep Kit also contains a mixing container with a 16 ounce fill line.

Active Ingredients

Sodium Sulfate, USP

Potassium Sulfate, FCC

Magnesium Sulfate, USP

Inactive ingredients: sodium benzoate NF, sucralose, malic acid FCC, citric acid USP, flavoring ingredients, purified water USP.



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Section 4. First Aid Measures

Do not drink SUPREP Bowel Prep Kit solution that has not been mixed with water (diluted). It may increase your risk of nausea, vomiting, electrolyte disturbances and fluid loss (dehydration).

There are no known hazards from ingestion of the reconstituted solution. The known possible adverse reactions (>2%) are overall discomfort, abdominal distension, abdominal pain, nausea, and vomiting and headache.

Note to Physician: No specific antidote. Treatment should be based upon the judgment of the physician in response to reactions of the patient.

Section 5. Fire-Fighting Measures

Not considered to be a fire hazard. Liquid solution (sodium, potassium, and magnesium).

Section 6. Accidental Release Measures

Steps to be taken if Material is Released or Spilled: Contain spilled material if possible. Collect in suitable and properly labeled containers.

Personal Precautions: Spilled material may cause a slipping hazard. Use appropriate Safety Equipment and Personal Protection Equipment (PPE) to contain and collect liquid material. Dispose of collected material properly.

Environmental Precautions: Prevent from entering into soil, ditches, sewers, waterways and /or ground water.

Section 7. Handling and Storage

SUPREP® BOWEL PREP KIT is a drug product available on a prescription basis only in the USA. Storage precautions taken for prescription products should be observed. Store at 20° to 25° C (68° to 77°F). Excursions permitted between 15° to 30° C (59° to 86° F). See USP controlled room temperature.

Section 8. Exposure Controls and Personal Protection

SUPREP® BOWEL PREP KIT

Two 6-ounce bottles of SUPREP® (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution. Use safety glasses for eye protection and Personal Protective Equipment in case of liquid spill clean-up.



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Sodium Sulfate, USP

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Potassium Sulfate, FCC

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminant below the exposure limit.

Personal Protection:

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Magnesium Sulfate, USP

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:

Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

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Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Inactive Ingredients

Sodium benzoate NF, sucralose, malic acid FCC, citric acid USP, flavoring ingredients, purified water USP.

Section 9. Physical and Chemical Properties

SUPREP® BOWEL PREP KIT

Each Kit contains: Two 6-ounce bottles of SUPREP® (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution.

Sodium Sulfate, USP

Physical state and appearance:

Solid. (Crystals solid. Crystalline powder. Granular solid. Powdered solid.)

Odor: Odorless.

Taste: Bitter. Saline.

Molecular Weight: 142.06 g/mole

Color: White.

pH (1% soln/water): Not available.

Boiling Point: 1100°C (2012°F)

Melting Point: 888°C (1630.4°F)

Critical Temperature: Not available.

Specific Gravity: 2.671 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility: Soluble in cold water, hydrogen iodide, and glycerol. Insoluble in alcohol.

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Potassium Sulfate, FCC

Physical state and appearance: Solid.

Odor: Not available.

Taste: Not available.

Molecular Weight: 174.26 g/mole

Color: Not available.

pH (1% soln/water): Not available.

Boiling Point: 1689°C (3072.2°F)

Melting Point: 1067°C (1952.6°F)

Critical Temperature: Not available.

Specific Gravity: 2.66 (Water = 1)

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility: Partially soluble in cold water.

Magnesium Sulfate, USP

Physical state and appearance: Solid.

Odor: Not available.

Taste: Not available.

Molecular Weight: 120.38 g/mole

Color: Not available.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: Not available.

Critical Temperature: Not available.

Specific Gravity: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility: Easily soluble in cold water.

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Inactive Ingredients

Sodium Benzoate, NF

Odor: Odorless.

Taste: Sweetish, astringent.

Molecular Weight: 144.11 g/mole

Color: White.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: >300°C (572°F)

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

Vapor Density: 4.97 (Air = 1)

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility: Easily soluble in cold water, hot water.

Sucralose

Physical state and appearance: Clear Solution

Odor: Slight Characteristic Odor

pH : 4-5

Boiling Point: 103C (217°F)

Freezing Point: 2°C (36°F)

Specific Gravity: 1.12 g/ml

Vapor Pressure: 24.0 mm Hg

Odor Threshold: Not available.

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Malic Acid, FCC

Physical state and appearance: Solid. (Crystalline powder.)

Odor: Odorless.

Taste: Not available.

Molecular Weight: 134.09 g/mole

Color: White. Colorless.

pH (1% soln/water): Not available.

Boiling Point: Decomposition temperature: 150°C (302°F)

Melting Point: 131°C (267.8°F) - 132 C

Critical Temperature: Not available.

Specific Gravity: 1.601 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: 0% (v/v).

Odor Threshold: Not available.

Water/Oil Dist. Coeff: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, methanol, acetone.

Solubility: Soluble in cold water, methanol. Partially soluble in acetone. Very slightly soluble in diethyl ether. Solubility in methanol @ 20 deg.: 82.70 g/100 g solvent Solubility in diethyl ether@ 20 deg. C: 0.84 g/100 g solvent Solubility in ethanol @ 20 deg. C: 45.53 g/100 g solvent Solubility in acetone @ 20 deg. C: 17.75 g/100 g solvent Solubility in dioxane @ 20 deg. C: 22.70 g/100 g solvent Solubility in water @ 20 deg. C: 55. 8 g/100 g solvent practically insolubility in benzene

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Citric Acid, USP

Physical state and appearance: Solid. (Crystalline powder)

Odor: Odorless.

Taste: Acid. (Strong.)

Molecular Weight: 192.13 g/mole

Color: Not available.

pH (1% soln/water): Not available.

Boiling Point: Decomposes.

Melting Point: 153°C (307.4°F)

Critical Temperature: Not available.

Specific Gravity: 1.665 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff: The product is more soluble in water; $\log(\text{oil/water}) = -1.7$

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, diethyl ether.

Solubility: Soluble in cold water, hot water, diethyl ether. Insoluble in benzene.

Flavoring Ingredients

N/A

Purified Water, USP

N/A

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Section 10. Stability and Reactivity

SUPREP® BOWEL PREP KIT

SUPREP® is stable when stored at the recommended storage conditions, Store at 20° to 25°C (68° to 77°F). Excursions permitted between 15° to 30°C (59° to 86°F). See USP controlled room temperature.

Sodium Sulfate, USP

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess dust generation, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, metals.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:

Hygroscopic. Sodium sulfate reacts violently with magnesium. Also incompatible with aluminum, potassium, mercury, lead, calcium, silver, barium, ammonium ions, and strontium. Sulfates give precipitates with salts of lead, barium, strontium, and calcium. Silver and mercury form slightly soluble salts. Alcohol precipitates most sulfates out of solution.

Special Remarks on Corrosivity:

The rates of corrosion of iron and steel in water are a function of the specific mineral quality as well as the alkalinity and pH values. Sodium sulfate ... is a strong contributor to the rate of corrosion. For example, in water with 400 mg/l of alkalinity (as CaCO₃) at pH 7, the corrosion rate will be zero at 200 mg/l of Na₂SO₄, but when the concentration of sodium sulfate is 400 mg/l, the corrosion rate will be about 100 mg per square cm per day.

Potassium Sulfate, FCC

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Not available.

Incompatibility with various substances: Not available.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: No.

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Magnesium Sulfate, USP

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Not available.

Incompatibility with various substances: Not available.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: No.

Inactive Ingredients

Sodium Benzoate, NF

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, dust generation

Incompatibility with various substances: Reactive with oxidizing agents.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity: Hygroscopic; keep container tightly closed.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Sucralose

Stability: The product is stable.

Malic Acid, FCC

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, alkalis.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity: Also incompatible with amines, and alkali metals.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.



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Citric Acid, USP

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, reducing agents, metals, alkalis.

Corrosivity: Corrosive in presence of aluminum, of zinc, of copper. Non-corrosive in presence of glass.

Special Remarks on Reactivity: Incompatible with oxidizing agents, potassium tartrate, alkali, alkaline earth carbonates and bicarbonates, acetates, and sulfides, metal nitrates

Special Remarks on Corrosivity: Will corrode copper, zinc, aluminum and their alloys.

Polymerization: Will not occur.

Flavoring Ingredients

N/A

Purified Water, USP

N/A

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Section 11. Toxicological Information

SUPREP® BOWEL PREP KIT

The sulfate salts of sodium, potassium, and magnesium contained in SUPREP Bowel Prep Kit were administered orally (gavage) to rats and dogs up to 28 days up to a maximum daily dose of 5 g/kg/day (approximately 0.9 and 3 times for rats and dogs, respectively, the recommended human dose of 44 g/day or 0.89 g/kg based on the body surface area). In rats, the sulfate salts caused diarrhea and electrolyte and metabolic changes, including hypochloremia, hypokalemia, hyponatremia, lower serum osmolality, and high serum bicarbonate. Significant renal changes included increased fractional sodium excretion, increased urinary sodium and potassium excretion and alkaline urine in both male and females. In addition, creatinine clearance was significantly decreased in females at the highest dose. No microscopic renal changes were seen. In dogs, the sulfate salts caused emesis, excessive salivation, excessive drinking of water, and abnormal excreta (soft and/or mucoid feces and/or diarrhea) and increased urine pH and sodium excretion.

Sodium Sulfate, USP

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD₅₀): 5989 mg/kg [Mouse].

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans:

Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans:

May cause adverse reproductive effects (fetotoxicity) based on animal studies. Human data found May cause cancer (tumorigenic) based on animal studies. No human data found. Placental absorption of sulfate ion has been characterized. Sulfate ion levels at term are somewhat higher in fetal than in maternal blood.

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: May cause irritation, although it is not known to be an irritant. Eyes: May cause eye irritation. Ingestion: Saline cathartics (laxatives) are poorly absorbed from the gastrointestinal tract; hence, systemic toxicity is unlikely unless massive amounts have been ingested. Ingestion of large amounts may cause gastrointestinal (digestive) tract irritation with abdominal pain, nausea, vomiting, and diarrhea. Low hazard for usual industrial handling. Inhalation: May cause respiratory tract irritation. Low hazard for usual industrial handling.

Potassium Sulfate, FCC

Routes of Entry: Absorbed through skin. Eye contact. Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD₅₀): 6600 mg/kg [Rat].

Chronic Effects on Humans: The substance is toxic to lungs, mucous membranes.



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Other Toxic Effects on Humans:

Hazardous in case of skin contact (irritant), of ingestion, of inhalation. Slightly hazardous in case of skin contact (permeator).

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans: Not available.

Magnesium Sulfate, USP

Routes of Entry: Ingestion.

Toxicity to Animals: LD₅₀: Not available. LC₅₀: Not available.

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans:

Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Human: passes through the placenta, excreted in maternal milk.

Special Remarks on other Toxic Effects on Humans: Not available.

Inactive Ingredients

Sodium Benzoate, NF

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD₅₀): 1600 mg/kg [Mouse].

Chronic Effects on Humans:

TERATOGENIC EFFECTS: Classified POSSIBLE for human. DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female, Reproductive system/toxin/male [SUSPECTED]. May cause damage to the following organs: blood, the reproductive system, liver, central nervous system (CNS).

Other Toxic Effects on Humans:

Hazardous in case of skin contact (irritant), of inhalation. Slightly hazardous in case of ingestion.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans:

May cause adverse reproductive effects and birth defects (teratogenic). May affect genetic material (mutagenic)

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: Dust may cause mechanical irritation. Inhalation: May cause respiratory tract irritation. Ingestion: Ingestion of large amounts may cause gastrointestinal tract irritation with gastric pain, nausea, and vomiting. May also affect behavior/central nervous system (tremor, convulsions, change in motor activity), and respiration (dyspnea). Chronic Potential Health Effects: Ingestion: Prolonged or repeated ingestion may

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affect behavior/central nervous system (symptoms similar to acute exposure) as well as liver, metabolism, blood, and urinary system.

Sucralose

Acute Studies: Sucralose is a non-toxic food additive. Oral rat LD₅₀ > 10 g/Kg; Oral mouse LD₅₀ > 16 Kg (no mortality at the highest tested doses.)

Malic Acid, FCC

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity for Malic acid (LD₅₀): 1600 mg/kg [Rat].

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: Causes skin irritation. Inhalation: Causes respiratory tract irritation. Ingestion: Moderately toxic by ingestion. May be harmful if swallowed. May cause nausea, vomiting, diarrhea. May affect behavior and respiration causing weakness, and respiratory distress and cyanosis. Chronic Potential Health Effects: Skin: Prolonged or repeated skin contact may cause dermatitis. Eyes: Prolonged or repeated eye contact may cause conjunctivitis.

Citric Acid, USP

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD₅₀): 3000 mg/kg [Rat].

Chronic Effects on Humans: May cause damage to the following organs: teeth.

Other Toxic Effects on Humans:

Hazardous in case of inhalation (lung irritant). Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion.

Special Remarks on Toxicity to Animals: LDL [Rabbit] - Route: oral; Dose: 7000mg/kg

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: Causes mild to moderate skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material. Eyes: Causes moderate to severe eye irritation and possible injury. Ingestion: May cause gastrointestinal (digestive) tract irritation with nausea, vomiting, diarrhea. Excessive intake may cause erosion of teeth and hypocalcemia (calcium deficiency in blood). May affect behavior/central nervous system (tremor, convulsions, muscle contraction or spasticity). Inhalation: Causes moderate respiratory tract

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and mucous membrane irritation. Chronic Potential Health Effects: Frequent intake of citrated beverages may cause erosion of dental enamel and irritation of mucous membranes.

Flavoring Ingredients

N/A

Purified Water, USP

N/A

Section 12. Ecological Information

SUPREP® BOWEL PREP KIT

Dispose of container and unused contents in accordance with federal, state and local environmental control regulations. Dispose of waste material in an appropriate container. Spills - Should not be left on floor (makes it slippery). Disposal - Burn in an approved incinerator in accordance with all federal, state and local requirements.

Sodium Sulfate, USP

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Potassium Sulfate, FCC

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are more toxic.

Special Remarks on the Products of Biodegradation: Not available.



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Magnesium Sulfate, USP

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are more toxic.

Special Remarks on the Products of Biodegradation: Not available.

Inactive Ingredients

Sodium Benzoate, NF

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Sucralose

Sucralose is biodegradable and poses no risk to the environment. Sucralose and its breakdown products are non-toxic to plant and animal life, are not fat-soluble, and do not accumulate in plant or animal tissue.

Malic Acid, FCC

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.

Special Remarks on the Products of Biodegradation: Not available.



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Citric Acid, USP

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Flavoring Ingredients

N/A

Purified Water, USP

N/A

Section 13. Disposal Considerations

SUPREP® BOWEL PREP KIT

Each Kit contains: Two 6-ounce bottles of SUPREP® (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution. Each SUPREP Bowel Prep Kit also contains a mixing container with a 16 ounce fill line.

Waste Disposal:

Dispose of container and unused contents in accordance with federal, state and local environmental control regulations.

Section 14. Transport Information

SUPREP® BOWEL PREP KIT

DOT Classification: Not a DOT controlled material (United States).

Special Provisions for Transport: Follow all applicable Regulations that pertain to shipping Pharmaceutical Finished Product



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Section 15. Regulatory Information

REGULATORY INFORMATION:

SUPREP Bowel Prep Kit is a drug product available on a prescription basis only in the US. Storage precautions taken for prescription products should be observed. Store only as instructed in the original container.

In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

The information presented herein is presented in good faith and is, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we make no guarantee of results, and assume no liability for damages incurred by the use of this material. No warranty, expressed or implied is given.

Regulatory requirements are subject to change and may differ from one location to another. Therefore, it is the buyer's responsibility to ensure that its activities comply with federal, state and local laws.

Section 16. Other Information

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