SAFETY DATA SHEET

GoLYTELY ®
PEG-3350 and Electrolytes for Oral Solution
A Prescription Drug Product

Section 1. Product and Company Identification

Product Name	GoLYTELY®
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)

External - May cause eye irritation. Prolonged or repeated skin exposure is not likely to cause significant skin absorption. May cause a more severe response if skin is abraded. Prolonged or repeated exposure of damaged skin, as in burn wounds, may result in absorption.

Section 3. Composition/Information on ingredients

GoLYTELY® (Disposable Jug)	**PINEAPPLE FLAVOR GoLYTELY® (Disposable Jug)**	**GoLYTELY® (Packet)**
Polyethylene Glycol 3350, NF	Polyethylene Glycol 3350, NF	Polyethylene Glycol 3350, NF
Anhydrous Sodium Sulfate, USP	Anhydrous Sodium Sulfate, USP	Anhydrous Sodium Sulfate, USP
Sodium Bicarbonate, USP	Sodium Bicarbonate, USP	Sodium Bicarbonate, USP
Sodium Chloride, USP	Sodium Chloride, USP	Sodium Chloride, USP
Potassium Chloride, USP	Potassium Chloride, USP	Potassium Chloride, USP
	Flavoring ingredients	

Section 4. First Aid Measures

External - Wash off or irrigate affected area with water.
Inhalation - No adverse effects are anticipated by this route of exposure incidental to proper handling.
Ingestion - No adverse effects are anticipated by this route of exposure incidental to proper handling. If large amounts of concentrated solution or powder were ingested get medical attention. Water should be given in copious amounts to prevent dehydration.
Note to Practitioner - No specific antidote. Treatment should be based upon the judgment of the practitioner in response to reactions of the patient.

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Section 5. Fire-Fighting Measures

Not considered to be a fire hazard. The polyethylene glycol 3350 component has a flash point of >450° F (232° C).
Approximate extinguishing media are water fog, alcohol foam, and dry chemical.
Polyethylene glycol dust in air can be explosive. Prevent contact of dust and possible ignition sources.

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

Section 7. Handling and Storage

GoLYTELY® is a drug product available on a prescription basis only in the US and Canada. Storage precautions taken for prescription products should be observed.
Good general ventilation should be sufficient for most conditions. Use safety glasses for eye protection.

Section 8. Exposure Controls and Personal Protection

GoLYTELY®

Good general ventilation should be sufficient for most conditions. Use safety glasses for eye protection, gloves and other appropriate PPE (Personal Protection Equipment).

Polyethylene Glycol 3350, NF

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. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent.
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

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Anhydrous 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.

Sodium Bicarbonate 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. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent.
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.

Sodium Chloride 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.
Exposure Limits: Not available.

Potassium Chloride 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. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent.
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.

Pineapple Flavor (Powder)

Good general ventilation should be sufficient for most conditions. Use safety glasses for eye protection, gloves and other appropriate PPE.

Section 9. Physical and Chemical Properties

GoLYTELY®

GoLYTELY, supplied as a white powder, must be reconstituted with water before its use.

GoLYTELY is available in a polyethylene bottle or a foil packet.

Pineapple Flavor GoLYTELY is available in a polyethylene bottle.

Polyethylene Glycol 3350, NF

Appearance	
Physical state	Granules.
Color	White

Odor	Mild
Odor Threshold	No test data available
pH	4.5 - 7.5 ASTM E70 (5% aqueous solution)
Melting point/range	53 - 57 °C (127 - 135 °F) Literature
Freezing point	53 - 57 °C (127 - 135 °F) Literature
Boiling point (760 mmHg)	> 200 °C (> 392 °F) Calculated. Decomposes
Flash point	closed cup 246 °C (475 °F) ASTM D 93
Flammability (solid, gas)	No
Lower explosion limit	No test data available
Upper explosion limit	No test data available
Water solubility	67 % at 20 °C (68 °F) Measured
Auto-ignition temperature	No test data available
Explosive properties	no test data available
Oxidizing properties	no test data available
Percent volatility	no test data available

NOTE: The physical data presented above are typical values and should not be construed as a specification.

Anhydrous 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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Sodium Bicarbonate USP

Physical state and appearance: Solid.
Odor: Odorless.
Taste: Saline. Alkaline.
Molecular Weight: 84.01g/mole
Color: White.
pH (1% soln/water): Not available.
Boiling Point: Not available.
Melting Point: Not available.
Critical Temperature: Not available.
Volatility: Not available.
Odor Threshold: Not available.
Water/Oil Dist. Coeff: Not available.

Sodium Chloride USP

Physical state and appearance: Solid. (Solid crystalline powder.)
Odor: Slight.
Taste: Saline.
Molecular Weight: 58.44 g/mole
Color: White.
pH (1% soln/water): 7 [Neutral.]
Boiling Point: 1413°C (2575.4°F)
Melting Point: 801°C (1473.8°F)
Critical Temperature: Not available.
Specific Gravity: 2.165 (Water = 1)
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. Soluble in glycerol, and ammonia. Very slightly soluble in alcohol. Insoluble in Hydrochloric Acid.

Potassium Chloride USP

Physical state and appearance: Solid.
Odor: Odorless.
Taste: Saline. (Strong.)
Molecular Weight: 74.55 g/mole
Color: White.
pH (1% soln/water): Not available.
Boiling Point: 1420°C (2588°F)
Melting Point: 770°C (1418°F)
Critical Temperature: 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, hot water. Very slightly soluble in methanol, n-octanol.

Pineapple Flavor (Powder)

Safety Data
Form: Powder
Color: Off-white to white
Odor: conforms to standard
Flash point: N/A
Vapor pressure: N/A

Section 10. Stability and Reactivity

GoLYTELY

Stable. Degradation of bicarbonate and polyethylene glycol components may occur at elevated temperatures. At very high temperatures salt components may decompose to form toxic oxides and chlorides.

Polyethylene Glycol 3350, NF

Reactivity: No data available
Chemical stability: Thermally stable at typical use temperatures.
Possibility of hazardous reactions: Polymerization will not occur.

Conditions to avoid: Product can oxidize at elevated temperatures. Generation of gas during decomposition can cause pressure in closed systems. Avoid static discharge.
Incompatible materials: Avoid contact with: Strong acids. Strong bases. Strong oxidizers.
Hazardous decomposition products: Decomposition products depend upon temperature, air supply and the presence of other materials. Decomposition products can include and are not limited to: Carbon dioxide. Alcohols. Ethers. Aldehydes. Carboxylic acids. Polymer fragments.

Anhydrous 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 $CaCO_3$) at pH 7, the corrosion rate will be zero at 200 mg/l of Na_2SO_4, but when the concentration of sodium sulfate is 400 mg/l, the corrosion rate will be about 100 mg per square cm per day.

Sodium Bicarbonate, USP

Stability: The product is stable.
Instability Temperature: Not available.
Conditions of Instability: Incompatible materials, Moisture. Stable in dry air, but slowly decomposes in moist air.
Incompatibility with various substances: Reactive with acids.
Corrosivity: Non-corrosive in presence of glass.
Special Remarks on Reactivity:
Reacts with acids to form carbon dioxide. Dangerous reaction with monoammonium phosphate or a sodium-potassium alloy.
Special Remarks on Corrosivity: Not available.
Polymerization: Will not occur.

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Sodium Chloride USP

Stability: The product is stable.
Instability Temperature: Not available.
Conditions of Instability: Incompatible materials, high temperatures.
Incompatibility with various substances: Reactive with oxidizing agents, metals, acids.
Corrosivity: Not considered to be corrosive for metals and glass.
Special Remarks on Reactivity:
Hygroscopic. Reacts with most non noble metals such as iron or steel, building materials (such as cement) Sodium chloride is rapidly attacked by bromine trifluoride. Violent reaction with lithium.
Special Remarks on Corrosivity: Not available.
Polymerization: Will not occur.

Potassium Chloride USP

Stability: The product is stable.
Instability Temperature: Not available.
Conditions of Instability: Incompatible materials
Incompatibility with various substances: Reactive with oxidizing agents, acids.
Corrosivity: Non-corrosive in presence of glass.
Special Remarks on Reactivity:
Hygroscopic. Incompatible with $KMnO_4$, H_2SO_4, BrF_3, and $BrCl_3$. May react violently with BrF_3.
Special Remarks on Corrosivity: Not available.
Polymerization: Will not occur.

Pineapple Flavor (Powder)

Conditions to avoid: Direct sources of heat
Chemical stability: Presents no significant reactivity hazard, by itself or in contact with water. Avoid contact with strong acids, alkali or oxidizing agents
Hazardous decomposition products: Carbon monoxide and unidentified organic compounds may be formed during combustion.

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Section 11. Toxicological Information

GoLYTELY®

No Data is available for Toxicological Information

Polyethylene Glycol 3350, NF

Routes of Entry: Not available.
Toxicity to Animals:
Acute oral toxicity (LD_{50}): 4000 mg/kg [Rat]. Acute dermal toxicity (LD_{50}): 20000 mg/kg [Rabbit].
Chronic Effects on Humans: Not available.
Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant, permeator), 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: Not available.

Anhydrous Sodium Sulfate, USP

Routes of Entry: Inhalation. Ingestion.
Toxicity to Animals: Acute oral toxicity (LD_{50}): 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.

Sodium Bicarbonate USP

Routes of Entry: Inhalation. Ingestion.
Toxicity to Animals: Acute oral toxicity (LD_{50}): 3360 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:
Sodium Bicarbonate as produced genetic effects in rats (unscheduled DNA synthesis). However, no affects have been found in humans.
Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: May cause mild skin irritation. Eyes: May cause mild eye irritation. Inhalation: May cause respiratory tract irritation. Symptoms may include coughing and sneezing. Ingestion: Symptoms of overexposure to Sodium Bicarbonate include thirst, abdominal pain, gastroenteritis, and inflammation of the digestive tract. Chronic Potential Health Effects: Skin: Repeated or prolonged skin contact may cause irritation, drying or cracking of the skin. Ingestion and Inhalation: Chronic toxicity usually occurs within 4 to 10 days following ingestion of very large amounts. Repeated or prolonged ingestion or inhalation of large amounts may cause metabolic abnormalities, and sodium retention. Metabolic abnormalities such as acidosis, hypernatremia, hypochloremia, alkalosis, hypocalcemia, or sodium retention may affect the blood, kidneys, respiration (cyanosis, apnea secondary to metabolic acidosis or pulmonary edema), and cardiovascular system (tachycardia, hypotension). Severe toxicity may also affect behavior/central nervous system/nervous system. Neurological changes may result from metabolic abnormalities. These may include fatigue, irritability, dizziness, mental confusion, paresthesia, seizures, tetany, cerebral edema Medical Conditions Aggravated by Exposure: Persons with pre-existing skin conditions might have increased sensitivity. Predisposing conditions that contribute to a mild alkali syndrome include, renal disease, dehydration, and electrolyte imbalance, hypertension, sarcoidosis, congestive heart failure, edema, or other sodium retaining conditions.

Sodium Chloride USP

Routes of Entry: Inhalation. Ingestion.
Toxicity to Animals:
WARNING: THE LC_{50} VALUES HEREUNDER ARE ESTIMATED ON THE BASIS OF A 4-HOUR EXPOSURE. Acute oral toxicity (LD50): 3000 mg/kg [Rat.]. Acute dermal toxicity (LD_{50}): >10000 mg/kg [Rabbit]. Acute toxicity of the dust (LC_{50}): >42000 mg/m3 1 hours [Rat].
Chronic Effects on Humans: MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast.
Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.
Special Remarks on Toxicity to Animals: Lowest Published Lethal Dose (LDL) [Man] - Route: Oral; Dose: 1000 mg/kg

Special Remarks on Chronic Effects on Humans:
Causes adverse reproductive effects in humans (fetotoxicity, abortion) by intraplacental route. High intake of sodium chloride, whether from occupational exposure or in the diet, may increase risk of TOXEMIA OF PREGNANCY in susceptible women (Bishop, 1978). Hypertonic sodium chloride solutions have been used to induce abortion in late pregnancy by direct infusion into the uterus (Brown et al, 1972), but this route of administration is not relevant to occupational exposures. May cause adverse reproductive effects and birth defects in animals, particularly rats and mice (fetotoxicity, abortion, musculoskeletal abnormalities, and maternal effects (effects on ovaries, fallopian tubes) by oral, intraperitoneal, intraplacental, intrauterine, parenteral, and subcutaneous routes. While sodium chloride has been used as a negative control n some reproductive studies, it has also been used as an example that almost any chemical can cause birth defects in experimental animals if studied under the right conditions (Nishimura & Miyamoto, 1969). In experimental animals, sodium chloride has caused delayed effects on newborns, has been fetotoxic, and has caused birth defects and abortions in rats and mice (RTECS, 1997). May affect genetic material (mutagenic)
Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: Causes eye irritation. Ingestion: Ingestion of large quantities can irritate the stomach (as in overuse of salt tablets) with nausea and vomiting. May affect behavior (muscle spasicity/contraction, somnolence), sense organs, metabolism, and cardiovascular system. Continued exposure may produce dehydration, internal organ congestion, and coma. Inhalation: Material is irritating to mucous membranes and upper respiratory tract.

Potassium Chloride USP

Routes of Entry: Inhalation. Ingestion.
Toxicity to Animals: Acute oral toxicity (LD_{50}): 1500 mg/kg [Mouse].
Chronic Effects on Humans: May cause damage to the following organs: blood, cardiovascular system.
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 affect genetic material. Passes through the placental barrier in animal.
Special Remarks on other Toxic Effects on Humans:
Actute Potential Health Effects: Skin: May cause skin irritation Eye: Dust may cause eye irritation. Inhalation: Dust may cause respiratory tract irritation. Low hazard for usual industrial handling Ingestion: May affect behavior (coma, change in motor activity, listlessness, vertigo, mental confusion, paresthesias, general weakness, flaccid paralysis), metabolism, blood (change in clotting factor, electrolytic imbalance), cardiovascular (hypotension, circulatory disturbances, cardiac arrhythmias, heart block), and respiratory, gastrointestinal (irritation of GI tract, nausea, vomiting, diarrhea, abdominal discomfort, purging), and urinary(impairment of renal function) systems. Acute potassium intoxication by mouth is rare because large single doses usually induce vomiting, and because in the absence of pre-existing kidney damage potassium is rapidly excreted. Maximal nontoxic oral dose of KCl in man varies from 0.2g to 1 g of potassium/kg/day depending upon efficiency of individual excretory mechanism; lower doses sometimes cause impairment of renal function as shown by reduced inulin, and urea clearance.
Chronic Potential Health Effects: May affect blood and cardiovascular system.

Pineapple Flavor (Powder)

No Data available

Section 12. Ecological Information

GoLYTELY®

Spills - Should not be left on floor (makes it slippery). Do not breathe dust.
Disposal - Burn in an approved incinerator in accordance with all federal, state and local requirements.

Polyethylene Glycol 3350, 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 products of degradation are more toxic.

Anhydrous 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.

Sodium Bicarbonate 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.

Sodium Chloride 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.

Potassium Chloride 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.

Pineapple Flavor (Powder)

Avoid contamination of soil, ground and surface water.

Section 13. Disposal Considerations

GoLYTELY®

Waste Disposal: Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14. Transport Information

GoLYTELY®

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: GoLYTELY® is a drug product available on a prescription basis only in the US and Canada. 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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