

MSDS - Material Safety Data Sheet

Product Name: Lactulose Solution

MSDS No.: 779

I. Basic Information:

Manufacturer: Hi-Tech Pharmacal Co., Inc

Address: 369 Bayview Avenue

City, ST Zip: Amityville, NY 11701

Emergency Contact:

Emergency Telephone Number: 631-789-8228

Contact: Jesse Kirsh, QA Director

Information Telephone Number: 631-789-8228

Last Update: 11/04/2003

Chemical State: Liquid Gas Solid

Chemical Type: Pure Mixture



0	Health
2	Flammability
0	Reactivity
B	Pers. Protection

II. Ingredients:

Trade Secret

CAS No.	Chemical Name	% Range	EHS		IARC		SARA		OSHA PEL	ACGIH TLV	Other Limits
			NTP		SUB Z	313					
4818-18-2	Lactulose Solution										

III. Hazardous Identification:

Hazard Category:

Acute Chronic Fire Pressure Reactive

Hazardous Identification Information:

None

IV. First Aid Measures:

Route(s) of Entry:

Ingestion, Inhalation and skin contact

Health Hazards (Acute and Chronic):

Material is a liquid drug dosage form intended for human use.

Always follow prudent laboratory practices. Consult the package insert for further information.

Signs and Symptoms:

WARNING:

A theoretical hazard may exist for patients being treated with lactulose solution who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy.

If desired see package insert for detailed information.

Medical Conditions Generally Aggravated by Exposure:

Material is a liquid drug dosage form intended for human use.

Always follow prudent laboratory practices. Consult the package insert for further information.

Emergency and First Aid Procedures:

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Eye: Hold eyelids open and flush with steady stream of water for 15 minutes. See an eye doctor or physician immediately.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of the skin with plenty of soap and water. If irritation develops get medical attention.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs.

Ingestion: Call a physician or poison control center if over dosing has occurred.

Other Health Warnings:**OVERDOSAGE:**

Signs and Symptoms;

There have been no reports of accidental overdosage. In the event of overdosage, it is expected that diarrhea and abdominal cramps would be the major symptoms. Medication should be terminated.

V. Fire Fighting Measures:

Flash Point: >140F

Lower Explosive Limit: N/A

Upper Explosive Limit: N/A

F.P. Method: Tag closed

Fire Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as necessary.

Special Fire Fighting Procedures:

With small quantities use carbon dioxide extinguisher.

For large fires use ample quantities of water with dry chemicals or foam as necessary.

Unusual Fire and Explosion:

With small quantities use carbon dioxide extinguisher.

For large fires use ample quantities of water with dry chemicals or foam as necessary.

VI. Accidental Release Measures:**Steps to be Taken in Case Material is Released or Spilled:**

No special precautions. Pick up in the most efficient manner.

Soak up with sawdust, sand, oil dry or other absorbent material.

VII. Handling and Storage:**Precautions to be Taken:**

Keep container tightly closed.

Store between 59 - 86 F. Do not freeze.

Other Precautions:

Under recommended storage conditions, a normal darkening of color may occur. Such darkening is characteristic of sugar solutions and does not affect therapeutic action. Prolonged exposure to temperatures above 86F or to direct light may cause extreme darkening and turbidity which may be pharmaceutically objectionable. If this condition develops, do not use. Prolonged exposure to freezing temperatures may cause change to a semi-solid, too viscous to pour. Viscosity will return to normal upon warming to room temperature.

VIII. Exposure Controls/Personal Protection:**Ventilation Requirements:**

Under normal use and handling no protective equipment is required.

Personal Protective Equipment:

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Under normal use and handling no protective equipment is required.

Protective Gloves: Recommended

Eye Protection: Splash proof safety Glasses

IX. Physical and Chemical Properties:

Boiling Point: N/A

Melting Point: N/A

Evaporation Rate (Butyl Acetate = 1): Same as water

Vapor Pressure (mm Hg.): N/A

Specific Gravity (H₂O = 1): 1.33000

Vapor Density (AIR = 1): >1

Solubility In Water: Soluble

Appearance and Odor: Colorless to slightly yellow

Other Information: Use only as directed.

X. Stability and Reactivity:

Stability:

Stable at normal temperature conditions.

Avoid sources of ignition

Incompatibility (Materials to Avoid):

Strong oxidizer

Decomposition/By Products:

Does not undergo explosive decomposition

Hazardous Polymerization:

Will not occur

XI. Toxicological Information:

If desired see package insert for detailed information.

XII. Ecological Information:

N/A

XIII. Disposal Considerations:

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State / Provincial and Local Regulations.

XIV. Transport Information:

The known properties of this material do not constitute a hazard as defined by the U.S. Department of Transportation.

XV. Regulatory Information:

N/A

XVI. Other Information:

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To the best of our knowledge the information contained herein is accurate as of the date hereof. Any determination as to the suitability of the product for any particular purpose, its safe use or disposal, shall be the responsibility of the user. The information contained herein is in no way intended to supplement, modify, or supercede the information provided in the package insert with respect to the product for medical purposes. Please refer to the product insert or label for information regarding the use of the product for medical purposes. We reserve the right to revise the Material Safety Data Sheets periodically as new information becomes available.