



IN CASE OF EMERGENCY CALL:
National Poison Control 800-222-1222

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Lactulose Solution
CAS No: 15687-27-1
Chemical Name: 4-O-β-D-galactopyranosyl-D-fructofuranose
Chemical Formula: $C_{12}H_{22}O_{11}$
Molecular Weight: 342.30
Product Use: Treatment of constipation.

Manufacturer's Name: VistaPharm, Inc.
Address: 7265 Ulmerton Road
Largo, FL 33771

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Lactulose USP (10g/15mL) active ingredient

Please refer to current package insert for other components.

3. HAZARDS IDENTIFICATION

Primary Route of Entry: Ingestion. Not hazardous.

Overdoseage: Diarrhea and abdominal cramps.

Medical Conditions

Aggravated by Exposure: Contraindicated in patients who require a low galactose diet.

4. FIRST AID MEASURES

Eye Exposure: Flush with running water for 15 minutes holding eyelid open. Then contact physician.

Skin Exposure: Remove contaminated area with water. If skin irritation occurs, contact physician.

Inhalation: Remove to fresh air and contact physician or poison control center.

Ingestion: Overuse: Contact a physician or poison control center.

Special Protection Information

Ventilation: Not required under normal conditions of therapeutic use.

Respiratory Protection: Not required under normal conditions of therapeutic use.

Protective Gloves and Clothing: Not required under normal conditions of therapeutic use.

Eye Protection: Safety glasses recommended.

5. FIRE AND EXPLOSION HAZARD

This product does not pose a fire hazard.

Flash Point: Not determined.

Extinguishing Media: Water spray, multipurpose dry chemical, carbon dioxide or foam as appropriate for the surrounding fire or material.

Fire Fighting Procedures: Use self contained breathing apparatus and protective clothing.

Hazardous Combustion Products: Not determined.

6. ACCIDENTAL RELEASE MEASURES

If Material is Spilled or Released: Wearing suitable protective clothing, absorb liquid on to appropriate absorbent material and place into a container for disposal. Impermeable gloves and eye protection should be worn as a minimum precaution. Additional protective clothing/equipment may be needed depending on the extent of the spill. The spill area should be ventilated and decontaminated after material has been picked up.

7. HANDLING AND STORAGE

Handling: Observe good industrial hygiene practices. Shake well before using.

Storage: Store at controlled temperature of 20° to 25°C (68° to 77°F). Keep out of reach from children.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

OSHA Exposure Limits: None

Engineering Controls: Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Personal Protection: Not required when handling final product. If containers are compromised or exposure is likely wear: goggles, lab coat, and gloves.

Recommended Facilities: Eye wash, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor:	Orange-colored, cherry-flavored
Melting Point (deg. C):	Not determined.
Boiling Point (deg. C):	Not determined.
Solubility:	Soluble
pH Range:	2.5 to 6.5

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable
Conditions to Avoid:	Avoid excessive heat, freezing, and direct light.
Incompatibility:	Not determined.
Hazardous Decomposition:	May produce noxious or toxic products.
Hazardous Polymerization:	Does not occur.

11. TOXICOLOGICAL INFORMATION

Other Studies:

Pregnancy: *Pregnancy category B.* Reproduction studies have been performed in mice, rats, and rabbits at doses up to 3 or 6 times the usual human oral dose and have revealed no evidence of impaired fertility or harm to the fetus due to lactulose. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lactulose solution is administered to a nursing

Pediatrics: Safety and effectiveness in pediatric patients have not been established.

12. ECOLOGICAL INFORMATION

Environmental Effects: Not determined.

13. WASTE DISPOSAL INFORMATION

Waste Disposal Considerations: Dispose of this material in accordance with applicable international, national, state and local waste disposal regulations.

At Home: Discard away from children's reach.

14. TRANSPORTATION INFORMATION

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

15. REGULATORY INFORMATION

FDA: Lactulose Solution is an approved prescription medication.

Inventory Status: The material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use. This material is not listed on the DSL Inventory but is exempt.

16. DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: May 2010

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION