

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078398004

N/A



<b>IN CASE OF EMERGENCY</b> <b>Emergency Phone: (614) 276-4000</b>
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## Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Lactulose Solution USP		
Chemical Name: 4-O-Beta-D-galactopyranosyl-D-fructofuranose		
Synonyms: None		
Molecular Formula: C <sub>12</sub> H <sub>22</sub> O <sub>11</sub>		
Molecular Weight: 342.30		
CAS No: 4618-18-2		
Chemical Family: Laxative		
Product Use: Treatment for acute and chronic constipation		
Manufacturer's Name: <b>Boehringer Ingelheim Roxane Inc.</b>		
Address: <b>1809 Wilson Road Columbus, Ohio 43228</b>		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Lactulose (active ingredient)	4618-18-2	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as &lt;1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Liquid solution administered orally. Clear, amber, sweet-tasting liquid with 10 g/15 mL active ingredient.  Odor: Slight  <b>WARNING!</b> May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.	
Primary Route(s) of Entry	Ingestion	
Potential Health Effects:	Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form.  Eye Contact: Not expected to be a hazard to the eye. Contact with eye may cause irritation, burning and redness.  Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.  Ingestion: May be harmful if ingested. Ingestion may cause intestinal cramps, nausea and vomiting. In rare cases, it can cause severe diarrhea and dehydration.	
Toxicity Data:	See Section 11	
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause dehydration, hypokalemia, and hypernatremia.	
Target Organs:	Gastrointestinal tract	
4. FIRST AID MEASURES		
Eye Exposure	Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.	
Skin Exposure	Wash with soap and water. Get medical attention if symptoms occur.	

Ingestion	Call a physician or poison control center immediately.				
Inhalation	Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.				
<b>5. FIRE AND EXPLOSION HAZARDS</b>					
Flammability	Lower: N/A		Upper: N/A		
Flash Point	Not Applicable				
Extinguishing Media	Use water spray, dry chemical, carbon dioxide, foam or material appropriate for fire in surrounding area				
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus.				
Unusual Fire/Explosion Hazards	Not Applicable				
Hazardous Combustion Products	Carbon dioxide, carbon monoxide				
<b>6. ACCIDENTAL RELEASE INFORMATION</b>					
<b>STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED:</b> Use appropriate personal protective equipment (see Section 8). Wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.					
<b>7. PRECAUTIONS FOR SAFE HANDLING AND USE</b>					
Precautions Handling Significant Quantities of Liquid:	Observe good industrial hygiene practices.				
Storage	Store at 20° to 25°C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs. Do not freeze.				
<b>8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT</b>					
Exposure Limits	None				
Engineering Controls	Not required when handling liquid or containers. Good ventilation should be used. 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, Gloves				
Recommended Facilities	Eye wash, washing facilities				
<b>9. PHYSICAL / CHEMICAL CHARACTERISTICS</b>					
Appearance	Clear, amber liquid	Melting point	Not available	Solubility in water	Soluble
Odor	Slight	Boiling point	Not available	Specific Gravity	Not available
Taste	Sweet-tasting	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available
<b>10. STABILITY AND REACTIVITY DATA</b>					
Stability	Stable				
Incompatibility	None known				
Hazardous Decomposition	Oxides of carbon				
Conditions to Avoid	Excessive heat, light				

<b>Hazardous Polymerization</b>	Will not occur.
<b>11. TOXICOLOGICAL INFORMATION</b>	
<p><b>Acute Toxicity:</b></p> <p><b>Active Ingredient:</b>                      LD50 Oral (rat): 18160 mg/kg                      LD50 Oral (mouse): 31000 mg/kg</p> <p><b>Carcinogenicity:</b> Not listed as a carcinogen by NTP, IARC Monographs or OSHA.</p>	
<b>12. ENVIRONMENTAL IMPACT INFORMATION</b>	
No information is currently available on the environmental impact of this product.	
<b>13. DISPOSAL INFORMATION</b>	
<p><b>Waste Disposal Considerations:</b> Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.</p> <p><b>At home:</b> Discard away from children's reach.</p>	
<b>14. TRANSPORTATION INFORMATION</b>	
<p>This product is not subject to the regulations for the safe transport of hazardous chemicals.</p> <p>DOT: Not regulated                      TDG: Not regulated                      IATA: Not regulated                      IMDG: Not regulated</p>	
<b>15. REGULATORY INFORMATION</b>	
<p><b>DEA:</b> Lactulose is not a controlled substance.</p> <p><b>FDA:</b> Lactulose is an approved prescription medication.</p> <p><b>Inventory Status:</b> This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&amp;D or drug use.                      This material is not listed on the DSL Inventory but is exempt.</p>	
<b>16. OTHER DATA</b>	
<p><b>ABBREVIATIONS:</b>                      N/A – not applicable</p> <p><b>Prepared by:</b> Boehringer Ingelheim Roxane, Inc.</p> <p><b>References:</b></p> <ol style="list-style-type: none"> <li>1. Lactulose Solution USP, Package Insert, Boehringer Ingelheim Roxane, Inc. , Columbus, Ohio</li> <li>2. RTECS No. LS6965000 – Fructofuranose, 4-O-beta-D-galactopyranosyl-, D-</li> <li>3. Ariel Websight. Regulatory and ChemExpert Database.</li> <li>4. PDR – Physicians Desk Reference</li> </ol>	
Date: 09/13/2008 - New MSDS	
<b>SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION</b>	

*The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. Boehringer Ingelheim Roxane, Inc. assumes no responsibility or liability resulting from the use of this information.*

## 1. Identification

<b>Product identifier</b>	<b>Lactulose Solution USP</b>
<b>Other means of identification</b>	None.
<b>Recommended use</b>	Treatment of constipation
<b>Recommended restrictions</b>	None known.

### Manufacturer/Importer/Supplier/Distributor information

<b>Company name</b>	Boehringer Ingelheim Roxane Inc.
<b>Address</b>	1809 Wilson Road Columbus, Ohio 43228
<b>Telephone</b>	(614) 276-4000
<b>Emergency phone number</b>	(614) 276-4000

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.

### Label elements

<b>Hazard symbol</b>	None.
<b>Signal word</b>	Warning
<b>Hazard statement</b>	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

### Precautionary statement

<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials. Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F). Keep from freezing.
<b>Disposal</b>	Incineration of waste at an approved USEPA incinerator is recommended.

<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
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## 3. Composition/information on ingredients

### Substances

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

Chemical name	Common name and synonyms	CAS number	%
4-O-β-D-galactopyranosyl-D-fructofuranose		4618-18-2	10g/15mL

<b>Composition comments</b>	Refer to Physician's Desk Reference for common components present at <1%
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## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Side effects most commonly reported are flatulence and intestinal cramps. Nausea and vomiting have also been reported.

**Indication of immediate medical attention and special treatment needed** There have been no reports of over dosage. In the event of over dosage, it is expected that diarrhea and abdominal cramps would be the major symptoms. Medication should be terminated.

**General information** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical** During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions** Use water spray to cool unopened containers.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** No unusual fire or explosion hazards noted.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).

**Methods and materials for containment and cleaning up** Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling** Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.

**Conditions for safe storage, including any incompatibilities** Store away from incompatible materials (see Section 10 of the SDS). Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F). Do not freeze.

## 8. Exposure controls/personal protection

**Occupational exposure limits** No exposure limits noted for ingredient(s).

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** Ventilation should be matched to conditions.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

#### Skin protection

**Hand protection** For consumer use, no unusual precautions are necessary.

**Other** None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory protection** None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

**9. Physical and chemical properties**

<b>Appearance</b>	Clear, amber liquid
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Clear amber.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Soluble
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

**10. Stability and reactivity**

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Exposure to light.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

**11. Toxicological information****Information on likely routes of exposure**

<b>Inhalation</b>	Not expected to be hazardous in final pharmaceutical form.
<b>Skin contact</b>	Not expected to be hazardous in final pharmaceutical form.
<b>Eye contact</b>	Not expected to be hazardous in final pharmaceutical form. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Ingestion may cause irritation and malaise.

**Symptoms related to the physical, chemical and toxicological characteristics** Side effects most commonly reported are flatulence and intestinal cramps. Nausea and vomiting have also been reported.

**Information on toxicological effects**

**Acute toxicity** May be harmful if swallowed in large quantities.

Product	Species	Test Results
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Lactulose Solution USP (CAS Mixture)

**Acute**

*Oral*

LD50	Rat	> 30 ml/kg
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**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation.

**Respiratory or skin sensitization**

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** This product is not reported to cause mutagenic effects in humans.

**Carcinogenicity** Long-term studies in animals have not been conducted to evaluate carcinogenic potential

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity** Pregnancy Category B

There are 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 needed.

It is not known whether this product is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when administering to a nursing woman

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Not classified.

**Further information** See package insert.

**12. Ecological information**

**Ecotoxicity** The product is not classified as environmentally hazardous.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Other adverse effects** None.

**13. Disposal considerations**

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

**US federal regulations** This 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.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** No

### SARA 313 (TRI reporting)

Not regulated.

**Other federal regulations** Drug Enforcement Administration (DEA): Lactulose is not a controlled substance.

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

Not listed.

### US state regulations

#### US. Massachusetts RTK - Substance List

Not regulated.

#### US. New Jersey Worker and Community Right-to-Know Act

Not listed.

#### US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

#### US. Rhode Island RTK

Not regulated.

#### US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	30-December-2014
<b>Revision date</b>	-
<b>Version #</b>	01
<b>References</b>	<ol style="list-style-type: none"> <li>1) Lactulose Solution, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio</li> <li>2) PDR – Physicians Desk Reference.</li> <li>3) Ariel Websight. Regulatory and ChemExpert Database.</li> </ol>

<b>Disclaimer</b>	Boehringer Ingelheim Roxane Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.
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