



SAFETY DATA SHEET

Issue Date: 11/22/2024

Revision Date: New SDS

Revision Number: 01

1. IDENTIFICATION

Product identifier: Lactulose Powder sachet

Product Codes: 0121-0965-30 (10G); 0121-1930-30 (20G)

Supplier Name and Address: Pharmaceutical Associates, Inc.
201 Delaware Street

Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – treatment of constipation

Restrictions on use: Use only as directed

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Lactulose	4618-18-2	100%

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdose, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing large amounts may cause gastrointestinal irritation, nausea, and diarrhea.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for large unintended ingestion or overdose.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Water spray, foam, or dry powder.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire. High concentrations of dust in the air may present a dust explosion hazard.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain spill. Damaged sachets should be carefully collected to avoid generation of airborne dust. Wipe up powder with a damp wipe. If large amounts of powder are released, eliminate ignition sources and carefully sweep up, avoid the creation of airborne dust. Place in appropriate container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid generating and inhaling dust. Avoid contact with eyes.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Exposure guidelines:**

Lactulose (as particulates not otherwise classified)	5 mg/m ³ (respirable) 15 mg/m ³ (total dust) TWA OSHA PEL
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Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety glasses or goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White suspension

Odor: Peppermint

Physical State: Solid (crystalline powder)	Color: White
Odor: Odorless	pH: Not applicable
Melting point/freezing point: 164-169°C	Boiling Point: Not applicable
Flash point: Not applicable	Particle Characteristics: No data available
Flammability: Not flammable but will burn in fire	VOC: Not applicable
Flammable limits: LEL: Not applicable	UEL: Not applicable
Vapor pressure: Not applicable	Relative Vapor density: Not applicable
Relative density: No data available	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Kinematic Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of dust may cause irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing large amounts may cause gastrointestinal irritation, nausea, and diarrhea.

Skin contact: May cause mild irritation.

Eye contact: May cause mild irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens.

Reproductive Toxicity: Components are not classified as reproductive toxins.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values:

Lactulose: Oral rat LD50 18,160 mg/kg, Oral mouse LD50 31,000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No specific data available. Toxic effects are not expected.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

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Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: New SDS

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