

Section 1: Identification

1.1 Identification

Product name: Lactulose Solution, USP
 Synonyms: Fructofuranose, 4-O-beta-D-galactopyranosyl-, D-; D-Lactulose
 NDCs: 0116-4005-15, 0116-4005-30, 0116-4005-08, 0116-4005-16, 0116-4005-32

1.2 Details of the supplier of the safety data sheet

Xttrium Laboratories, Inc. 1200 East Business Center Drive
 Mt. Prospect, IL 60056

1.3 Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture: Pharmaceutical Agent

1.4 Emergency telephone number

Emergency number: (773) 268-5800

Section 2: Hazard(s) Identification

2.1 Classification of the substance or mixture

Physical Hazards: Combustable liquid, Category 4
 Health Hazards: Not classifiable, no symbols
 Signal word: Warning
 Hazard statements: H227 Combustable liquid
 Precautionary statements: P210 Keep away from flames and hot surfaces, no smoking
 P280 Wear laboratory appropriate PPE
 P370 + P378 In case of fire: water, carbon dioxide, dry chemical, or foam to extinguish
 P403 + P235 Store in well-ventilated place, keep cool

2.2 Label elements

No GHS US labeling applicable

2.3 Other hazards

No additional information available

2.4 Unknown acute toxicity (GHS US)

Not applicable

Section 3: Composition/Information on ingredients

3.1 Substances

3.2 Mixtures

Name	Chemical Formula	Molecular Weight	CAS Number	EC Number	Concentration
Lactulose	C ₁₂ H ₂₂ O ₁₁	342.30 g/mol	4618-18-2	225-027-7	90-110% labeled amount

Section 4: First aid measures

4.1 Description of first aid measures

First-aid measures after inhalation: Move individuals to fresh air.
 First-aid measures after skin contact: Wash with soap and water for 20 minutes. Seek medical advice if skin irritation develops or persists.
 First-aid measures after eye contact: Immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists get medical attention.
 First-aid measures after ingestion: Do not induce vomiting. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation: None under normal use.
 Symptoms/effects after skin contact: May cause skin irritation.
 Symptoms/effects after eye contact: May cause eye irritation.
 Symptoms/effects after ingestion: May be harmful if swallowed. Nausea, diarrhea, or flatulence may occur.

4.3 Indication of any immediate medical attention and special treatment needed

Theoretical hazard: Lactulose patients should not undergo electrocautery procedures.
 (ex: proctoscopy or colonoscopy)

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Dry chemical, foam, carbon dioxide, water fog.
 Unsuitable extinguishing media: None.

5.2 Special hazards arising from the substance or mixture

Fire hazard: Not flammable.
 Explosion hazard: None known.

5.3 Advice for firefighters

Protection during firefighting: Firefighters should wear full protective gear.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures

For non-emergency personnel: No additional information available.
 For emergency responders: No additional information available.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and materials for containment and cleaning up

For containment: Stop the flow of material, if this is without risk.
 Methods for cleaning up: Confine spill and soak up with absorbent. Place in an approved container and dispose in accordance with local, state, and federal regulations.

6.4 Reference to other sections

No additional information available.

Section 7: Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling: Avoid contact with eyes. Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Store at 68°F - 77°F (20°C - 25°C)
 Normal darkening may occur. Do not freeze. Keep away from oxidizers or strong acids.

Section 8: Expose controls/personal protection

8.1 Control parameters

Lactulose (4618-18-2): 10 mg/m³ TWA

8.2 Exposure controls

Appropriate engineering controls: Provide adequate general and local exhaust ventilation.
 Hand protection: Wear impervious gloves to minimize skin contact.
 Eye protection: Chemical goggles or safety glasses.
 Skin and body protection: Wear suitable working clothes and laboratory PPE.
 Respiratory protection: None required under normal product handling conditions.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Chemical formula: C₁₂H₂₂O₁₁
 Molecular weight: 342.30 g/mol
 Specific gravity: 1.33000
 Physical state: Liquid, clear to golden yellow color
 pH: 2.5 - 6.5

Safety Data Sheet

Odor and odor threshold:	Odorless, no data available
Vapor pressure:	> 1 @ 25°C
Relative evaporation rate:	Water = 0.3 (when butyl acetate = 1)
Solubility:	Water soluble
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Flammability (solid, gas):	No data available
Relative vapor density at 20°C:	No data available
Relative density:	No data available
Partition coefficient n-octanol/water: (Log P _{ow})	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
Explosion limits:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

9.2 Other information

No additional information available.

Section 10: Stability and reactivity**10.1 Reactivity**

No additional information available.

10.2 Chemical stability

The product is stable at normal handling and storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

None.

10.5 Incompatible materials

Strong oxidizers.

10.6 Hazardous decomposition products

Not determined.

Section 11: Toxicological information**11.1 Information on toxicological effects**

Acute toxicity:	Not classified
Reproductive toxicity:	Not classified
Skin corrosion/irritation:	Not classified
Serious eye damage/irritation:	Not classified
Respiratory or skin sensitization:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity (NPT, IARC, OSHA):	Not classified
STOT-single and -repeated exposure:	Not classified
Aspiration hazard:	Not classified

Section 12: Ecological information

12.1 Toxicity

No additional information available.

12.2 Persistence and degradability

No additional information available.

12.3 Bioaccumulative potential

No additional information available.

12.4 Mobility in soil

No additional information available.

12.5 Other adverse effects

No additional information available.

Section 13: Disposal conciderations

13.1 Waste treatment methods (product and/or packaging)

Disposal recommendations: Dispose of contents/container in accordance with local, regional, national, or international regulations.

Section 14: Transport information

Department of Transportation (DOT): In accordance with DOT
Not applicable

Section 15: Regulatory Information

15.1 US Federal regulations

No additional information available.

15.2 US State regulations

No additional information available.

Section 16: Other Information

	Health:	0
NFPA:	Flammability:	2
	Reactivity:	0