

Xttrium Laboratories, Inc. Lactulose Solution, USP (for Oral Administration)

Safety Data Sheet

Section 1: Identification

1.1 Identification

Product name: Lactulose Solution, USP
Synonyms: Fructofuranose, 4-O-beta-D-galactopyranosyl-, D-; D-Lactulose
0116-4005-15, 0116-4005-30, 0116-4005-08, 0116-4005-16,
NDCs: 0116-4005-32, 0116-4005-11, 0116-4005-40, 0116-4005-41, 0116-4005-10

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.

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4.2 Most important symptoms and effects, both acute and delayed

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| 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

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| Theoretical hazard: | Lactulose patients should not undergo electrocautery procedures. (ex: proctoscopy or colonoscopy) |
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Section 5: Firefighting measures

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

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| Protection during firefighting: | Firefighters should wear full protective gear. |
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Section 6: Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures

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| 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

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| 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

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| Precautions for safe handling: | Avoid contact with eyes. Wash thoroughly after handling. |
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7.2 Conditions for safe storage, including any incompatibilities

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| 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. |
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Section 8: Expose controls/personal protection

8.1 Control parameters

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| Lactulose (4618-18-2): | 10 mg/m ³ TWA |
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8.2 Exposure controls

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| 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

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| Chemical formula: | C ₁₂ H ₂₂ O ₁₁ |
| Molecular weight: | 342.30 g/mol |
| Specific gravity: | 1.33000 |
| Physical state: | Liquid, clear to golden yellow color |
| pH: | 2.5 - 6.5 |
| 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

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| 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

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|------|-------------------------------|--------------------------------------|
| 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 considerations

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| 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

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| Department of Transportation (DOT): | Not applicable. The product is not regulated as a hazardous material under the United States Department of Transportation (DOT) regulations. |
| International Air Transport Association (IATA): | Not applicable/Not regulated. This product is not regulated as a dangerous good under the rules of the International Air Transport Association (IATA). |

Section 15: Regulatory Information

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| 15.1 | US Federal regulations | No additional information available. |
| 15.2 | US State regulations | No additional information available. |

Section 16: Other Information

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|-------|---------------|---|
| | Health: | 0 |
| NFPA: | Flammability: | 2 |
| | Reactivity: | 0 |