

Safety Data Sheet

Issuing date: 02/23/2015

Revision date:

01/09/2017

Revision number:

01

1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: Lactulose Solution USP

Other mean of identification

Product code(s): 0121-0577-08, 0121-0577-16, 0121-0577-32, 0121-4577-15, 0121-4577-30, 0121-1154-30, 0121-4577-40, 0121-1154-40, 0121-1154-00

UN-Number: NA

Synonyms: Lactulose Syrup

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as a laxative.

Uses advised against: Do not use except as prescribed.

Supplier address/information

Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

2. Hazards Identification

Classification

This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family:

Mixture

Statement of Hazard:

Slightly hazardous in case of skin contact (irritant, sensitizer), of eye contact (irritant), of ingestion (irritant), of inhalation (irritant).

Additional Hazard Information

Short term:

Can cause nausea, diarrhea, and flatulence.

Long term:

Prolonged or repeated ingestion may affect the urinary system, and metabolism (weight loss, dehydration), blood (normocytic anemia), endocrine system (adrenal gland).

Known Clinical Effects:

Excessive dosing can lead to diarrhea with potential complications such as loss of fluids, hypokalemia, and hyponatremia.

EU Indication of danger:

Not classified.

Emergency overview

Safety Data Sheet

Issuing date: 02/23/2015

Revision date: 01/09/2017

Revision number: 01

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

3. Composition/Information on ingredients

Chemical name	CAS-No	g/mL	Trade Secret
Lactulose Concentrate	4618-18-2 (lactulose)	10 g/15mL	
Pineapple, orange flavor	Mixture		X
FD&C Yellow No. 6	2783-94-0		X

4. First aid measures

Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel.

Skin contact:

Wash contaminated area thoroughly with soap and water. If irritation persists, contact medical personnel.

Inhalation:

Remove to fresh air and contact medical personnel.

Ingestion:

Overdosage or accidental ingestion – Do not induce vomiting. Contact medical personnel or poison control center.

Safety Data Sheet

Issuing date: 02/23/2015

Revision date: 01/09/2017

Revision number: 01

Most important symptoms/effects, acute and delayed

Skin: May cause skin irritation, and possible hyper sensitization.

Eyes: May cause eye irritation.

Inhalation: May cause respiratory track irritation.

Ingestion: May cause irritation of the digestive tract with nausea, diarrhea and flatulence. May also affect metabolism, behavior/central nervous system (muscle weakness, ataxia) respiration (Dyspnea, respiratory depression).

Indication of immediate medical attention and special treatment needed, if necessary

NA

Notes to Physician: NA

5. Fire-fighting measures

Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical

May burn emitting toxic fumes.

Explosion data:

Not applicable

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures.
Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

7. Handling and storage

Precautions for safe handling

Handling:

No special handling required for hazard control under conditions of normal product use.

Safety Data Sheet

Issuing date: 02/23/2015

Revision date: 01/09/2017

Revision number: 01

Conditions for safe storage, including any incompatibilities

Storage: No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products: Not applicable.

8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Lactulose Concentrate	Not Available	Not Available	Not Available
Pineapple, orange flavor	Not Available	Not Available	Not Available
FD& C Yellow No. 6	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Not required under normal conditions of use.

Respiratory protection: Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures: Wash hands thoroughly after use.

Safety Data Sheet

Issuing date: 02/23/2015

Revision date:

01/09/2017

Revision number:

01

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Solution
Odor: Slight
Appearance: Yellow- orange viscous liquid
Odor threshold: Not available

Property	Values	Remarks/Method
pH	2.5 – 6.5	Current USP
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	1.3 – 1.4	Current USP
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information

VOC content (%): None

Safety Data Sheet

Issuing date: 02/23/2015

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10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
Conditions to avoid	Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible materials	As a precautionary measure, keep away from strong oxidizers
Hazardous decomposition products	None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information listed in the table below is for the individual components and not for the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Lactulose	18160 mg/kg Rat	Not Available	Not Available
Pineapple orange flavor	Not Available	Not Available	Not Available
FD&C Yellow No. 6	5000 mg/kg Mouse	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristics

Can cause nausea, diarrhea, and flatulence

Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

Numerical measures of toxicity – product

- No data available

Safety Data Sheet

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12. Ecological information

Ecotoxicity:

Environmental properties have not been thoroughly evaluated for this product. Releases to the environment should be avoided.

Persistence and Degradability

No data available

Bioaccumulation

No data available

Other adverse effects:

No data available

The following table includes data for the individual components.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Lactulose	Not Available	Not Available	Not Available	Not Available
Pineapple orange flavor	Not Available	Not Available	Not Available	Not Available
FD&C Yellow No. 6	Not Available	Not Available	Not Available	Not Available

13. Disposal considerations

Waste disposal methods

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

Contaminated packaging

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

14. Transport information

Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

15. Regulatory information

International inventories

TSCA:

Lactulose Solution USP is not listed on TSCA inventory; however the components Lactulose and FD&C Yellow No. 6 are listed.

Safety Data Sheet

Issuing date: 02/23/2015

Revision date: 01/09/2017

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EINECS:

Lactulose and FD&C Yellow No. 6 are listed on the EINECS inventory.

U.S. Federal regulations:

Not listed as dangerous goods.

SARA 311/312 Hazard categories:

Not Applicable

Clean Water Act

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA:

No components are listed under CERCLA.

California Proposition 65:

This product does contain any components which are listed under Proposition 65.

U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Lactulose					
Pineapple orange flavor					
FD&C Yellow No. 6					

U.S. EPA label information:

Not applicable

16. Other information

Prepared by:

Pharmaceutical Associates Regulatory Affairs

Issuing date:

02/23/2015

Revision date:

01/09/2017

Revision note:

01 – Updated NDC Number to include 00121-1154-30.

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet