

Trade Name: Lactose Monohydrate NF (Spray Dried)

1 Identification

1.1 Product identifier

Trade name: Lactose Monohydrate NF

Product Code: C6018

Application of the substance / the mixture: Pharma Excipient

1.2 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

SpecializedRx Products, LLC

3787 95th Ave NE Suite 100

Circle Pines, MN 55014 USA

www.specializedrx.com

sales@specializedrx.com

Information department:

Tel.: 1-888-512-1209

Fax: 1-612-424-8481

1.3 Emergency telephone number:

Emergency Telephone:

US: 1-888-512-1209

International: 1-888-512-1209

2 Hazard(s) identification

2.1 Classification of the substance or mixture

Material is considered hazardous because: combustible dusts may form in the air.

2.2 Label elements

Hazard pictograms



Signal word Warning

Precautionary
statements (GHS US)

: Keep container tightly closed and avoid heat/hot surfaces/sparks/open flames/ignition sources. Prevent dust accumulation.

2.3 Other hazards

Adverse human health effect(s) and symptom(s)

May cause eye irritation.

May cause skin irritation

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Ingestion of large amounts may cause gastrointestinal irritation.
Inhalation may cause respiratory tract irritation.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 Composition/information on ingredients

3.1 Chemical Characterization: Substance

3.2 Chemical Information

Chemical Name: D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1)

Botanical Name: Not applicable

Synonym: Milk sugar

Chemical Formula: C₁₂H₂₂O₁₁ · H₂O

CAS Number: 64044-51-5

Alternate CAS Number: Not applicable

Molecular Weight: 360.32 g/mol

3.3 Composition

CAS Number	Chemical Name	% By Weight
64044-51-5	D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1)	99 – 100%

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4 First-aid measures

4.1 Description of first aid measures

Eye contact: Flush eyes with water for 15 minutes. Remove contact lenses (if present) and flush again for 15 minutes. Seek medical advice if irritation occurs.

Inhalation: Remove victim to fresh air and provide supportive care e.g., a position in which breathing is comfortable. Seek medical advice if victim experiences discomfort or is not breathing.

Skin contact: Wash skin with water. Seek medical advice if irritation occurs.

Ingestion: Flush mouth with 2-4 cups of water. Do not give liquids to an unconscious person. Seek medical advice if irritation occurs.

4.2 Most important symptoms and effects, both acute and delayed

Eye contact: Exposure to airborne dust may result in eye irritation.

Inhalation: Exposure to airborne dust may result in irritation of the nose, throat and lungs.

Skin contact: No known significant effects or critical hazards.

Ingestion: No known significant effects or critical hazards.

4.3 Indication of any immediate medical attention and special treatment needed

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Perform symptomatic treatment. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

5 Fire-fighting measures

5.1 Extinguishing media

Use dry chemical powder, water spray jet, or foam.

5.2 Special hazards arising from the substance or mixture

High-pressure media may result in formation of an explosive dust-air mixture.
Combustion of this substance may result in the formation of hazardous gases i.e., carbon monoxide (CO) and carbon dioxide (CO₂).

5.3 Advice for firefighters

Protective equipment: In the event of fire, wear self-contained breathing apparatus.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

General measures: avoid dust formation, wear protective clothing. Avoid eye/skin contact; do not smoke while using.

Protective equipment: wear personal protective clothing (see chapter 8).

6.2 Environmental precautions:

Contain spillage.

6.3 Methods and material for containment and cleaning up:

Collect into properly labeled, suitable containers, using mechanical pick-up procedures. Avoid dust formation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

No relevant information available.

7 Handling and storage

7.1 Precautions for safe handling: Do not smoke near material. Avoid dust formation.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Store in well-closed containers, under dry and odor-free conditions.

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7.3 Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters

Components with limit values that require monitoring at the workplace:

Substance Name	Occupational exposure limits:
Dust limit	3 mg/m ³ alveolar fraction 10 mgm ³ respiratory fraction

Respiratory protection necessary at exposure limit excess; select a respirator that meets the appropriate standard or certification.

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

Wash hands before breaks and at the end of work and following usual precautionary measures for working with or handling chemicals. Do not eat/drink while working with material.

Breathing equipment:

Not required under normal use.

Eye Protection:

Not required under normal use

Protection of hands:

Chemical-resistant, impervious gloves complying with an approved standard should always be worn when handling chemical products if risk assessment determines this is necessary.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: Solid powder

Color: white

Odor: odorless

pH-value: Not applicable

Melting point/Melting range: 202°C

Boiling point/Boiling range: Not determined

Flash point: 93.33°C (Closed cup)

Flammability (solid, gaseous): Not applicable.

Ignition temperature: Not determined

Decomposition temperature: Not determined.

Auto igniting: Not determined

Danger of explosion: Product is not explosive.

Explosion limits: Product is not explosive.

Lower: Not determined

Upper: Not determined

Vapor pressure: Not determined

Density: Not determined

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Relative density (water = 1): 1

Relative Vapor density (air = 1): Not determined

Evaporation rate: Not determined.

Solubility in / Miscibility with Water: Soluble in cold water

Partition coefficient (n-octanol/water): Not determined.

Viscosity:

Dynamic: Not determined

Kinematic: Not determined

9.2 Other information: No further relevant information available.

10 Stability and reactivity

10.1 Reactivity: Stable under normal conditions; avoid electrostatic loading.

10.2 Chemical stability: Stable under normal conditions, no hazardous reactions.

10.3 Possibility of hazardous reactions: Avoid heat and open flame

10.4 Conditions to avoid: Avoid the creation of dust in the presence of ignition sources. Avoid strong-smelling materials.

10.5 Incompatible materials: Oxidizing materials

10.6 Hazardous decomposition products: Hazardous decomposition products should not be produced under normal conditions of storage and use.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

LD50 Rat oral (mg/kg)	>10g/kg (food)
LD50 Rat inhalative (mg/kg/4h)	n. d. a. (food)
LD50 Rat dermal (mg/kg)	n. d. a. (food)
to eye:	n. d. a. (food)

Primary irritant effect:

Eye contact: irritation and/or redness

Inhalation: respiratory tract irritation and/or coughing

Skin contact: no further information

Ingestion: no further information

Sensitization: Contains traces of milk protein: inhalation of dust may lead to sensitization in some allergic individuals

Additional toxicological information:

No data available.

12 Ecological information

No data available.

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13 Disposal considerations

13.1 Disposal Methods

Avoid or minimize waste generation whenever possible. Disposal of this product, solutions and byproducts should comply with local, state and federal regulations.

14 Transport information

14.1 UN-Number

DOT, ADR, ADN, IMDG, IATA

Not regulated for transport

14.2 UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

Not regulated for transport

14.3 Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

Class

Not regulated for transport

14.4 Packing group

DOT, ADR, IMDG, IATA

Not regulated for transport

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

UN "Model Regulation":

Void

15 Regulatory information

15.1 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

CAS #	Chemical Name	S.302 (EHS)	S.304 RQ	S.313 (TRI)
64044-51-5	D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1)	No	No	No

This material meets the EPA 'Hazard Categories' defined for SARA Title III Sections 311/312 as indicated:

<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Explosive	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Acute toxicity (any route of exposure)
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	Flammable (gases, aerosols, liquid or solid)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Skin Corrosion or Irritation
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Oxidizer (liquid, solid, gas)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Serious eye damage or eye irritation

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<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Self-reactive	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Respiratory or skin sensitization
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Pyrophoric (liquid or solid)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Germ cell mutagenicity
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Pyrophoric (gas)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Carcinogenicity
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Self-heating	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Reproductive toxicity
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Organic peroxide	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Specific target organ toxicity (single or repeated exposure)
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Corrosive to metal	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Aspiration hazard
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Gas under pressure (compressed gas)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Simple asphyxiant
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	In contact with water emits flammable gas	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	(Health) Hazard not otherwise classified (HNOC)
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Combustible gas	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	(Physical Hazard not otherwise classified (HNOC)

15.2 Hazardous components & Regulatory Lists

No additional information available.

16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

Department issuing SDS:

SpecializedRx Products, LLC

Quality Assurance

Contact: sales@specializedrx.com

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Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit