

### SECTION 1: Identification of the substance/mixture

#### 1.1. Product identifier

Product form : Substance  
 Substance name : Lactose, Monohydrate  
 CAS No. : 64044-51-5  
 Product code : LW-LACTOSE  
 Formula :  $C_{12}H_{22}O_{11} \cdot H_2O$   
 Synonyms : Milk Sugar

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Excipient material used in pharmaceutical applications

#### 1.3. Emergency telephone number

Emergency number : 1.800.424.9300 (USA)  
 +1.703.527.3887 (INT)

### SECTION 2: Hazards Identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Combustible dust

#### 2.2. Label elements

##### GHS-US labeling

Hazard pictograms (GHS-US) : None  
 Signal word (GHS-US) : Warning  
 Hazard statements (GHS-US) : May form combustible dust concentrations in air.  
 Precautionary statements (GHS-US) : None

#### 2.3. Other hazards

No additional information available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	GHS-US classification
Lactose, monohydrate	(CAS No.) 64044-51-5	100	Combustible Dust

#### 3.2. Mixtures

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Not applicable

### SECTION 4: Description of first aid measures

#### 4.1. Description of first aid measures

- First-aid measures general : If medical advice is needed, have product container or label at hand.
- First-aid measures after inhalation : If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Obtain medical attention if breathing difficulty persists.
- First-aid measures after skin contact : Rinse with plenty of water.
- First-aid measures after eye contact : Rinse with water while holding eyelids open. If eye irritation persists: Get medical advice and attention.
- First-aid measures after ingestion : Do not induce vomiting. Seek medical attention if a large amount is swallowed.

#### 4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries : Prolonged contact with large amounts of dust may cause mechanical irritation.
- Symptoms/injuries after inhalation : None under normal use. Overexposure may be irritating to the respiratory system.
- Symptoms/injuries after skin contact : None under normal use. Prolonged contact with a large amount of dust may cause mechanical irritation.
- Symptoms/injuries after eye contact : None under normal use. Prolonged contact with large amounts of dust may cause mechanical irritation.
- Symptoms/injuries after ingestion : None under normal use.
- Chronic symptoms : Prolonged inhalation of dust may cause respiratory irritation.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

- Suitable extinguishing media : Not considered flammable but will burn at high temperatures. Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None known.

#### 5.2. Special hazards arising from the substance or mixture

- Fire hazard : Combustible Dust. Dust explosion hazard in air.

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- Explosion hazard : Dust clouds can be explosive. Avoid dust clouds in combination with static electricity.
- Reactivity : Stable at ambient temperature and under normal conditions of use.
- 5.3. Advice for firefighters**
- Firefighting instructions : Do not breathe fumes from fires or vapors from decomposition.
- Protection during firefighting : Use normal individual fire protective equipment.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Handle in accordance with good industrial hygiene and safety practice. Good housekeeping is needed during storage, transfer, handling, and use of this material to avoid excessive dust accumulation.

#### 6.1.1. For non-emergency personnel

- Protective equipment : Not required for normal conditions of use.
- Emergency procedures : Collect as any solid. Ventilate area.

#### 6.1.2. For emergency responders

- Protective equipment : If possible, stop flow of product.
- Emergency procedures : Contain and collect as any solid. Ventilate area.

### 6.2. Environmental precautions

No additional information available

### 6.3. Methods and material for containment and cleaning up

- For containment : Contain and collect as any solid.
- Methods for cleaning up : Avoid generation of dust during clean-up of spills.

### 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 : Handle in accordance with good industrial hygiene and safety procedures. Good housekeeping is needed during storage, transfer, handling, and use of this material to avoid excessive dust accumulation. Take precautionary measures against static discharge.

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Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Protect from moisture. Store in a dry, cool place. Keep container tightly closed.

### 7.3. Specific end use(s)

Excipient material used in pharmaceutical applications

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

Appropriate engineering controls : Avoid dust production. Ensure adequate ventilation, especially in confined areas. Take precautionary measures against static discharges.

Personal protective equipment : Safety glasses.



Eye protection : Safety glasses.

Skin and body protection : Wear suitable protective clothing.

Respiratory protection : Not required for normal conditions of use. In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls : Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Consumer exposure controls : Wear recommended personal protective equipment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Powder

Color : White

Odor : Slight

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Odor threshold	: No data available
pH	: Slightly acidic
Concentration of pH solution	: 10 %
Relative evaporation rate (butyl acetate=1)	: Not applicable
Melting point	: 202 °C (396 °F)
Freezing point	: Not applicable
Boiling point	: Not applicable
Flash point	: No data available
Self-ignition temperature	: 360 - 470 °C (680 °F – 878 °F)
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: Not applicable
Relative vapor density at 20 °C	: Not applicable
Relative density	: Not applicable
Solubility	: Soluble. Water: 21.6 g/100ml at 25°C (77°F)
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosive properties	: See range below.
Oxidising properties	: None known
Explosive limits	: 30 - 125 g/m <sup>3</sup>

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable at ambient temperature and under normal conditions of use.

### 10.2. Chemical stability

Stable at standard temperature and pressure.

### 10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

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### 10.4. Conditions to avoid

Use good housekeeping practices during storage, transfer, and handling to avoid excessive dust accumulation.

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under conditions of fire this material may produce: Carbon dioxide. Carbon monoxide.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute 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	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

Lactose Monohydrate (64044-51-5)	
Persistence and degradability	Product is biodegradable.

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

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No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Sewage disposal recommendations : Do not dispose of waste into sewer.

Waste disposal recommendations : Dispose of waste material in accordance with all local, regional, national, and international regulations.

### SECTION 14: Transport information

In accordance with DOT / TDG / ADR / RID / ADNR / IMDG / ICAO / IATA

#### 14.1. UN number

No dangerous good in sense of transport regulations.

#### 14.2. UN proper shipping name

Not applicable

#### 14.3. Additional information

Other information : No supplementary information available.

#### Overland transport

No additional information available

#### Transport by sea

No additional information available

#### Air transport

No additional information available

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

No additional information available

#### 15.2. National regulations

No additional information available

#### 15.3. US State regulations

No additional information available

### SECTION 16: Other information

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