SAFETY DATA SHEET

Section 1 Identification of the substance/mixture and of the company/undertaking

Product Identifier:
Identification on the label/ Tradename: Lactose Monohydrate NF (Spray-dried)
Identification of the Product: CAS# 64044-51-5
Formula: \( \text{C}_{12}\text{H}_{22}\text{O}_{11} \)
RTECS #: OD9625000
Cl No.: Not Available
Synonyms: 4-O-beta-D-Galactopyranosyl-D-glucose monohydrate D-(+)-Lactose monohydrate; Milk Sugar

Relevant identified uses of the substance and uses advised against:
Identified Uses: Manufacture or Compounding of Substances
Uses Advised Against: Not information available

Name, address, and telephone number of the manufacturer:
Refer to Supplier
Name, address, and telephone number of the supplier:
Encore Scientific
801 West New Orleans Street Broken Arrow, OK, USA 74011
Supplier’s Telephone #
800-454-2304 Monday to Friday 8:00 am to 6:00 pm (Central time)
24 Hr. Emergency Tel #
INFOTRAC: (800) 535-5053 (Within Continental US and Canada); (352)323-3500 (International)

Section 2 Hazards Identification

Classification according to Regulation
Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Adverse physicochemical, human health and environmental effects
No additional information available

Label elements
Labelling according to Regulation (EC) No. 29 CFR 1910.1200:
Warning: May form combustible dust concentrations in air
Other hazards
Other hazards not contributing to the classification
Not Applicable

Section 3 Composition/information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose, Monohydrate</td>
<td>64044-51-5</td>
<td>100</td>
</tr>
</tbody>
</table>
Lactose Monohydrate NF (Spray-dried)

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Section 4 First aid measures

General Advice: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible). Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126)

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary

Eye Contact: Flush eye with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary

Most important symptoms and effects, both acute and delayed

Symptoms/injuries: None expected under normal conditions of use.

Symptoms/injuries Inhalation: None expected under normal conditions of use.

Symptoms/injuries Skin Contact: None expected under normal conditions of use.

Symptoms/injuries Eye Contact: None expected under normal conditions of use.

Symptoms/injuries Ingestion: None expected under normal conditions of use.

Chronic Symptoms: None expected under normal conditions of use.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically

Section 5 Fire-Fighting measures

Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.

Unsuitable extinguishing media: No information available

Special hazards arising from the substance or mixture

Fire hazard: Not considered flammable but may burn at high temperatures.

Explosion hazard: Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source creates potential combustible dust cloud

Reactivity: Carbon oxides

Advice for firefighters

Precautionary measures fire: Exercise caution when fighting any chemical fire.

Firefighting instructions: Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
Lactose Monohydrate NF (Spray-dried)

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Section 5 Fire-Fighting measures (continued)

Protection during firefighting: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear
Other information: Refer to Section 9 for flammability properties.

Section 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures
General measures: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Remove all sources of ignition. Avoid dust formation. Avoid dispersal of dust in the air. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Non-sparking tools should be used.
For non-emergency personnel
Protective equipment: Use appropriate personal protection equipment (PPE).
Emergency procedures: Evacuate unnecessary personnel.

For emergency responders
Protective equipment: Equip cleanup crew with proper protection.
Emergency procedures: Stop leak if safe to do so. Eliminate ignition sources. Ventilate area.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system.
Methods and material for containment and cleaning up
For containment: Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading
Methods for cleaning up: Sweep up and shovel into suitable containers for disposal. Use only non-sparking tools. Clean contaminated surface thoroughly.
Reference to other sections

Section 7 Handling and storage

Precautions for safe handling
Additional hazards when processed: All equipment used when handling the product must be grounded. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Keep away from incompatible materials, heat and sources of ignition.
Precautions for safe handling: Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe vapors/dust. Keep away from heat and sources of ignition
Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
Lactose Monohydrate NF (Spray-dried)

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Section 7 Handling and storage (continued)

Conditions for safe storage, including any incompatibilities
Technical measures: Comply with applicable regulations. Use explosion proof equipment. Proper grounding procedures to avoid static electricity should be followed.
Storage conditions: Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.
Incompatible products: Oxidizing agents.

Specific end use(s): Manufacture or Compounding of Substances

Section 8 Exposure Controls/Personal Protection

Control parameters
No hazardous control occupational exposure limits for this chemical

Exposure controls
Appropriate engineering controls: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment) It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in the handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

Personal protective equipment:

Materials for protective clothing:
Chemically resistant apron (materials and fabrics).

Hand protection:
Protective gloves.

Eye protection:
Safety glasses.

Skin and body protection:
Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection:
Effective dust mask. Wear respirator with dust filter

Environmental exposure controls: Do not allow the product to be released into the environment.

Consumer exposure controls: Do not eat, drink or smoke during use.
Section 9 Physical and chemical properties

Information on basic physical and chemical properties:

Physical state: Solid-Crystalline Powder
Color: White
Odor: Odorless
Odor threshold: No data available
pH: No data available
Evaporation rate: No data available
Melting point: 202-214°C/396-417.2°F
Freezing point: No data available
Boiling point: No data available
Molecular/Formula Weight: 360.31
Flash point: No data available
Auto-ignition temperature: 470°C/878°F
Decomposition temperature: No data available
Flammability (solid, gas): No data available
Vapor pressure: No data available
Relative vapor density at 20 °C: No data available
Relative density: No data available
Solubility: Soluble in Water
Partition coefficient: n-octanol/water: No data available
Viscosity: No data available
Explosive properties: No data available
Oxidizing properties: No data available
Explosive limits: No data available

Other information
No additional information available

Section 10 Stability and reactivity

Reactivity: Reactive with oxidizing agents
Chemical stability: Stable at normal conditions

Possibility of hazardous reactions
Hazardous polymerization will not occur.

Conditions to avoid
Heat. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Incompatible materials.
Section 10 Stability and reactivity (continued)

Incompatible materials
Oxidizing agents

Hazardous decomposition products
Carbon oxides (CO, CO₂).

Section 11 Toxicological information

Information on toxicological effects

Acute toxicity: Not classified
Chronic Toxicity: Prolonged or repeated ingestion of very large amounts may cause hypermotility and diarrhea

Skin corrosion/irritation: May cause skin irritation.
Serious eye damage/irritation: May cause eye irritation
Respiratory or skin sensitization: May cause irritation of respiratory tract
Germ cell mutagenicity: Not classified
Carcinogenicity: Not considered carcinogenic
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

Toxicity: No additional information available
Persistence and degradability: No additional information available
Bioaccumulative potential: No additional information available
Mobility in soil: No additional information available
Results of PBT and vPvB assessment: No additional information available

Other adverse effects
Other information: Avoid release to the environment.

Section 13 Disposal considerations

Waste treatment methods
Waste disposal recommendations
Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.
Ecology - waste materials: Empty containers should be taken for local recycling, recovery or waste disposal
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Section 14 Transport information

In accordance with ADR / RID / IMDG / IATA / ADN
UN number: Not regulated for transport
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental hazards: No supplementary information available.
Other information: No additional information available

Special precautions for user
Overland transport: No additional information available
Transport by sea: No additional information available
Air transport: No additional information available
Transport in bulk according to Annex II of MARPOL and the IBC Code
Not applicable

Section 15 Regulation information

Safety, health and environmental regulations/legislation specific for the substance or mixture
EU-Regulations
No REACH Annex XVII restrictions
National regulations
Not Applicable
Chemical safety assessment
No indication of danger

Section 16 Other information

Further information: This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Notice to reader:
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