

SAFETY DATA SHEET

Creation Date 29-Jul-2009 Revision Date 12-Mar-2024 Revision Number 6

1. Identification

Product Name Lactose monohydrate

Cat No. : 3.1070

CAS No 64044-51-5

Synonyms Lactin; Lactobiose; Milk Sugar

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

NEUTRON PHARMACHEMICAL CO

11, 3th Floor, Borjsaz Building, Azadi Ave, Tehran, Iran.

T-021-66906732-3 F-021-66581408 info@neutronco.com www.neutronco.com

Emergency Telephone Number

125

2. Hazard(s) identification

Classification

Classification under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements

None required

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

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Component	CAS No	Weight %
Lactose, monohydrate	64044-51-5	<=100

4. First-aid measures

Eye Contact Rinse skin with water. Get medical attention if symptoms occur.

Skin Contact Rinse skin with water. Get medical attention if symptoms occur.

Inhalation Remove to fresh air. Get medical attention if symptoms occur. If not breathing, give artificial

respiration.

Ingestion Do NOT induce vomiting. Get medical attention.

Most important symptoms and

effects

Notes to Physician

No information available.

No information available

Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Unsuitable Extinguishing Media No information available

Flash Point No information available Method - No information available

Autoignition Temperature

Explosion Limits

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO2).

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

HealthFlammabilityInstabilityPhysical hazards00N/A

6. Accidental release measures

Personal Precautions Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust

formation.

Environmental Precautions Avoid release to the environment. See Section 12 for additional Ecological Information.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Avoid dust formation. **Up**

7. Handling and storage

Lactose monohydrate

Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid

dust formation. Avoid contact with skin and eyes. Avoid ingestion and inhalation.

Storage. Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures None under normal use conditions.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protectionWear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection No special protective equipment required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical StateSolidAppearanceWhiteOdorOdorless

Odor Threshold

pH

No information available
No information available

Melting Point/Range 219 °C / 426.2 °F
Boiling Point/Range No information available
Flash Point No information available
No information available

Evaporation Rate negligible Flammability (solid,gas) No information available

Flammability or explosive limits

Upper No data available Lower No data available

Vapor Pressure negligible

Vapor Density

No information available

Specific Gravity 1.525

Solubility

Partition coefficient; n-octanol/water

Autoignition Temperature

Soluble in water

No data available

No information available

Autoignition Temperature

Decomposition Temperature

Viscosity

No information available
No information available
No information available

Molecular Formula C12 H22 O11 . H2 O

Molecular Weight 360.32

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Avoid dust formation. Excess heat. Incompatible products.

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Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO2)

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg. Oral LD50 Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg. **Dermal LD50** Based on ATE data, the classification criteria are not met. ATE > 5 mg/l. Mist LC50

Component Information

Toxicologically Synergistic

Products

No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

No information available Irritation

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Lactose, monohydrate	64044-51-5	Not listed				

Mutagenic Effects No information available

No information available. **Reproductive Effects**

Developmental Effects No information available.

No information available. **Teratogenicity**

STOT - single exposure None known STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

No information available **Endocrine Disruptor Information**

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

Bioaccumulation/ Accumulation No information available.

Mobility Will likely be mobile in the environment due to its water solubility.

13. Disposal considerations

Chemical waste generators must determine whether a discarded chemical is classified as a **Waste Disposal Methods**

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

	14. Transport information
DOT	Not regulated

TDG Not regulated IATA Not regulated IMDG/IMO Not regulated

15. Regulatory information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Lactose, monohydrate	64044-51-5	=	-	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical

Not applicable

Substances & Mixtures, Under TSCA Section 6(h) (PBT)

TSCA 12(b) - Notices of Export

Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Lactose, monohydrate	64044-51-5	-	-	-	Χ	-		Χ	Χ	-

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and Not a

Health Administration

Not applicable

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Lactose monohydrate

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations

Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Not applicable

Component		REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Lactose, monohydrate	64044-51-5	-	-	-

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Lactose, monohydrate	64044-51-5	Not applicable	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Other International Regulations

	Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Γ	Lactose, monohydrate	64044-51-5	Not applicable	Not applicable	Not applicable	Not applicable

	16. Other information	
Creation Date	29-Jul-2009	
Revision Date	12-Mar-2024	

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Revision Summary

SDS sections updated. 1. 3. 16.

Disclaimer

The information provided in this Safety Data Sheet 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text

End of SDS