

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	LACTOSE, NF (Monohydrate) (Spray Dried)
PRODUCT CODE	0316
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Based on available data, the classification criteria are not met.			
PICTOGRAM	Not Applicable			
SIGNAL WORD	Not applicable			
HAZARD STATEMENT(S)	May form combustible dust concentrations in air.			
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable.			
PRECAUTIONARY STATEMENT(S)	Prevention	Not applicable.		
	Response	Not applicable.		
	Storage	Not applicable.		
	Disposal	Not applicable.		
HMS CLASSIFICATION	Health Hazard	0	Flammability	0
	Reactivity	0	Personal Protection	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	4-O-β-D-Galactopyranosyl-α-D-glucopyronase, monohydrate
BOTANICAL NAME	Not applicable

SYNONYM (+)-Lactose
CHEMICAL FORMULA C₁₂H₂₂O₁₁ H₂O
CHEMICAL FAMILY Disaccharide
CAS NUMBER 64044-51-5
ALTERNATE CAS NUMBER Not applicable
MOLECULAR WEIGHT 360.3096
COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
LACTOSE (Monohydrate)	64044-51-5	613-418-9	100

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

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL May form combustible dust concentrations in air.
FLAMMABLE PROPERTIES May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA **Small fire:** dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
METHODS & MATERIAL FOR CONTAINMENT On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

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.

SECTION 7: HANDLING AND STORAGE
PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Preserve in tight containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: **LACTOSE (Monohydrate)** CAS #: **64044-51-5**

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS	Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.
BIOLOGICAL MONITORING	Not available
CONTROL BANDING	Not available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid				
DESCRIPTION	White or almost white, odorless, crystalline powder.				
SOLUBILITY	Freely but slowly soluble in water; practically insoluble in alcohol.				
ODOR	Nearly odorless				
FLAMMABILITY	May be combustible at high temperature				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	Not available	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(201 - 202) ^{°C} , (393.8-395.6) ^{°F}
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	4.5 - 7.5 (10%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	1.53	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25 ^{°C})	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION
ACUTE TOXICITY

Oral: Rat: LD50: (mg/kg): >10000
 Dermal: Rabbit LD50: (mg/kg): Not available
 Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE IRRITATION

Due to lack of data the classification is not possible.

RESPIRATORY SENSITIZATION

Due to lack of data the classification is not possible.

SKIN SENSITIZATION

Due to lack of data the classification is not possible.

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.

CARCINOGENICITY

OSHA LACTOSE is not listed.

NTP LACTOSE is not listed.

IARC LACTOSE is not evaluated.

California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITY

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Due to lack of data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Gastrointestinal disturbances.

POTENTIAL HEALTH EFFECTS

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion May be harmful if swallowed.

Skin May be harmful if absorbed through skin. May cause skin irritation.

Eyes May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available
 LC50: 96 Hr: Fish: (mg/L): Not available
 EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Not available.

BIOACCUMULATIVE POTENTIAL

Not available.

MOBILITY IN SOIL	Not available.
OTHER ADVERSE EFFECTS	Not available.
	This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA

HAZCHEM	Not applicable
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EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
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ENVIRONMENTAL HAZARDS	Not available
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SPECIAL SHIPPING INFORMATION	Not applicable
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SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Right-to-know		
			Appendix A	Appendix B	Pennsylvania	New Jersey	Massachusetts
LACTOSE (Monohydrate) 64044-51-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Work Health and Safety Regulations	Inventory of Industrial Chemicals
LACTOSE (Monohydrate) 64044-51-5	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	PIC - Prior Informed Consent Regulation	EC 2012/18
LACTOSE (Monohydrate) 64044-51-5	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

02/2026

SUPERSEDES

01/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.