

LACTOSE MONOHYDRATE

GHS Safety Data Sheet

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

LACTOSE ,MONOHYDRATE

OTHER NAMES

C12-H22-O11, D-lactose, 4-(beta-D-galactosido)-D-glucose, lactin, lactobiose, "milk sugar", "D-glucose, 4-O-beta-D-galactopyranosyl-"

PRODUCT USE

Pharmacy; infant foods; bacteriology; baking and confectionery; margarine and butter manufacture; manufacture of penicillin, yeast, edible protein, and riboflavin; culture media; adsorbent in chromatography. alpha-Lactose is the usual milk sugar and the lactose of pharmacy.

SUPPLIER

Company: S D FINE- CHEM LIMITED

Address:

315- 317, T.V. INDUSTRIAL ESTATE,

248, WORLI,

MUMBAI- 400030.INDIA.

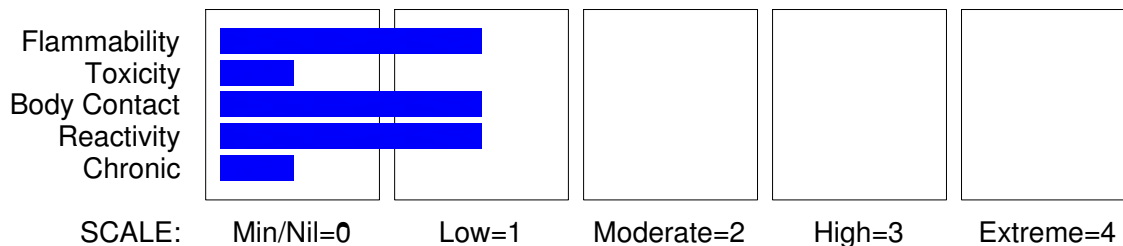
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HAZARD RATINGS



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Section 2 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

HAZARD

- Not hazardous
- No hazards determined using GHS criteria

PRECAUTIONARY STATEMENTS

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
alpha- lactose	63-42-3	> 99

Section 4 - FIRST AID MEASURES

SWALLOWED

- Immediately give a glass of water.
- First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

EYE

- If this product comes in contact with the eyes:
- Wash out immediately with fresh running water.
 - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
 - If pain persists or recurs seek medical attention.
 - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

- If skin or hair contact occurs:
- Flush skin and hair with running water (and soap if available).
 - Seek medical attention in event of irritation.

INHALED

- If dust is inhaled, remove from contaminated area.
- Encourage patient to blow nose to ensure clear passage of breathing.
- If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN

Treat symptomatically.

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Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD

- Solid which exhibits difficult combustion or is difficult to ignite.
 - Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
 - Dry dust can also be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
 - Build-up of electrostatic charge may be prevented by bonding and grounding.
 - Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
 - All movable parts coming in contact with this material should have a speed of less than 1-metre/sec.
- Combustion products include: carbon dioxide (CO₂).

FIRE INCOMPATIBILITY

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

MINOR SPILLS

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact by using protective equipment.
- Use dry clean up procedures and avoid generating dust.
- Place in a suitable labelled container for waste disposal.

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Section 6 - ACCIDENTAL RELEASE MEASURES

MAJOR SPILLS

No smoking, naked lights or ignition sources.

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact by using protective equipment and dust respirator.
- Prevent spillage from entering drains, sewers or water courses.
- Recover product wherever possible. Avoid generating dust.
- Sweep / shovel up.
- If required, wet with water to prevent dusting.
- Put residues in labelled plastic bags or other containers for disposal.
- Wash area down with large quantity of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise emergency services.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



+ + + + + +

+: May be stored together

O: May be stored together with specific precautions

X: Must not be stored together

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Limit all unnecessary personal contact.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

SUITABLE CONTAINER

Glass container.

Plastic container.

Multi-ply woven plastic or paper bag with sealed plastic liner

NOTE: Bags should be stacked, blocked, interlocked, and limited in height so that they are stable and secure against sliding or collapse.

- Check that containers are clearly labelled.

Packaging as recommended by manufacturer.

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Section 7 - HANDLING AND STORAGE

STORAGE INCOMPATIBILITY

Avoid reaction with oxidising agents.

STORAGE REQUIREMENTS

Store away from incompatible materials.

- Keep dry.
- Store under cover.
- Store in a well ventilated area.
- Store away from sources of heat or ignition.
- Observe manufacturer's storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- alpha- lactose:

CAS:63- 42- 3 CAS:5989- 81- 1 CAS:14641- 93- 1
CAS:64044- 51- 5 CAS:10039- 26- 6 CAS:89466- 76-
2 CAS:36570- 80- 6 CAS:73824- 63- 2 CAS:1336-
90- 9 CAS:35396- 14- 6 CAS:200734- 90- 3

PERSONAL PROTECTION



EYE

No special equipment for minor exposure i.e. when handling small quantities.

• OTHERWISE:

- Safety glasses with side shields.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

No special equipment needed when handling small quantities.

OTHERWISE: Wear chemical protective gloves, eg. PVC.

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

OTHER

No special equipment needed when handling small quantities.

- Overalls.
- Eyewash unit.

RESPIRATOR

Protection Factor	Half- Face Respirator	Full- Face Respirator	Powered Air Respirator
10 x ES	P1 Air- line*	- -	PAPR- P1 -
50 x ES	Air- line**	P2	PAPR- P2
100 x ES	-	P3	-
		Air- line*	-
100+ x ES	-	Air- line**	PAPR- P3

* - Negative pressure demand ** - Continuous flow.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.

For further information consult

your

Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
- Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.
- If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. Such protection might consist of:
 - (a): particle dust respirators, if necessary, combined with an absorption cartridge;
 - (b): filter respirators with absorption cartridge or canister of the right type;
 - (c): fresh-air hoods or masks
- Build-up of electrostatic charge on the dust particle, may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to efficiently remove the contaminant.

Type of Contaminant:

direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).

Air Speed:

1- 2.5 m/s (200- 500 f/min.)

2.5- 10 m/s (500- 2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range

Upper end of the range

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

- 1: Room air currents minimal or favourable to capture
- 2: Contaminants of low toxicity or of nuisance value only
- 3: Intermittent, low production.
- 4: Large hood or large air mass in motion

- 1: Disturbing room air currents
- 2: Contaminants of high toxicity
- 3: High production, heavy use
- 4: Small hood- local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated 2 metres distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Odourless, white, hard crystalline mass or powder with sweet taste.
Soluble in water, insoluble in chloroform and ether, very slightly soluble in alcohol.

PHYSICAL PROPERTIES

Solid.
Mixes with water.

Molecular Weight: 342.34
Melting Range (°C): 203.5 decomposes
Solubility in water (g/L): Soluble.
pH (1% solution): 7
Volatile Component (%vol): Not applicable.
Relative Vapour Density (air=1): Not available.
Lower Explosive Limit (%): Not available.
Autoignition Temp (°C): Not available.
State: Divided solid

Boiling Range (°C): Not applicable.
Specific Gravity (water=1): 1.53
pH (as supplied): Not applicable
Vapour Pressure (kPa): Negligible.
Evaporation Rate: Not applicable
Flash Point (°C): Not applicable
Upper Explosive Limit (%): Not available.
Decomposition Temp (°C): Not available.
Viscosity: Not available

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

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Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Although ingestion is not thought to produce harmful effects (as classified under EC Directives), the material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

EYE

Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
The dust may produce eye discomfort causing transient smarting, blinking.

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

INHALED

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

Principal routes of exposure are by accidental skin and eye contact and inhalation of generated dusts.
No human exposure data available. For this reason health effects described are based on experience with chemically related materials.
As with any chemical product, contact with unprotected bare skin; inhalation of vapour, mist or dust in work place atmosphere; or ingestion in any form, should be avoided by observing good occupational work practice.

TOXICITY AND IRRITATION

TOXICITY

Oral (rat) LD50: >10000 mg/kg
Equivocal tumorigenic agent by RTECS criteria.

IRRITATION

Nil Reported

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Section 12 - ECOLOGICAL INFORMATION

No data for alpha-lactose.

Section 13 - DISPOSAL CONSIDERATIONS

- Consult manufacturer for recycling options and recycle where possible .
- Consult State Land Waste Management Authority for disposal.
- Incinerate residue at an approved site.
- Recycle containers if possible, or dispose of in an authorised landfill.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM: None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:UN, IATA,
IMDG

Section 15 - REGULATORY INFORMATION

REGULATIONS

No regulations applicable

No data available for alpha-lactose as CAS: 63-42-3, CAS: 5989-81-1, CAS: 14641-93-1, CAS : 64044-51-5, CAS: 10039-26-6, CAS: 89466-76-2, CAS: 36570-80-6, CAS: 73824-63-2, CAS: 1336-90-9, CAS: 35396-14-6, CAS: 200734-90-3.

Section 16 - OTHER INFORMATION

INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
alpha- lactose	63- 42- 3, 5989- 81- 1, 14641 - 93- 1, 64044- 51- 5, 10039- 26- 6, 89466- 76- 2, 36570- 80- 6, 73824- 63- 2, 1336- 90- 9, 35396- 14- 6, 200734- 90- 3

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