Safety Information

Product group:	Lactose, Inhalation
Brand name:	Lactochem®, Lactohale®, Lactopress®, Pharmatose®, SuperTab®, Respitose®
Product description:	Lactose monohydrate
Document No.:	PD-0278 Page 1 of 5

Safety Information

- This product is not a dangerous product according to the applicable United Nations rules;
- The Safety Information is provided as a service to our customers and there is no legal obligation in the European Union to provide it in your national language and in the format of the Regulation (EC) 1907/2006 (consolidated);
- This safety information provides hazard information according to 29 CFR 1910.1200(a)(2);
- This document should be read in conjunction with the **Ingredient Declaration** and **Certificate of Standards/Product Specification** for the relevant product or product category.

1. Product and company identification

Product name: Lactochem®, Lactohale®, Lactopress®, Pharmatose®, SuperTab®, Respitose®

Cas Number: 64044-51-5: Official quote in current Japanese Pharmacopoeia / Official in Brazil(Anvisa)

Identified uses; Excipient used in the manufacturing of pharmaceutical products

Manufacturer/supplier identification: See Footer

2. Hazards Identification

No hazardous product as specified in the current EU legislation and in UN-rules.

GHS-US classification; combustible dust.

Warning! May form combustible dust concentrations in air (during processing)

3. Composition/information on ingredients

See Ingredient Declaration and the Product Specification
For D-(+)-Lactose monohydrate the following CAS number is applicable:
CAS No.: 64044-51-5: Official quote in current Japanese Pharmacopoeia / Official in Brazil (Anvisa)

EINECS No.: 200-559-2
RTECS No.: OD9625000

Molecular weight: 360,3 g/mol
Formula: $C_{12}H_{22}O_{11} \cdot H_2O$

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4. First aid measures

After inhalation: fresh air.
After skin contact: wash off with plenty of water.
After eye contact: rinse out with water.
After swallowing (large amounts): get medical attention.

5. Fire-fighting measures

Explosion; Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source (e.g., static electricity) is a potential dust explosion hazard
This product is flammable. Suitable extinguishing media: water, powder, spray foam, CO_2
In adaptation to materials stored in the immediate neighborhood.

6. Accidental Release measures

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.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Non sparking tools should be used.

7. Handling and storage

For safety reasons, store in the original unopened well closed container protected from solvents.
Close carefully after opening, avoiding spillage of powder.
Minimize dust generation and accumulation.
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.
Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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8. Exposure controls/personal protection

Respiratory protection required when dusts are generated.
Eye protection is required.
The use of hand protection is recommended.
Wash hands after working with substance.

It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen- deficient environment.
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).
Use only appropriately classified electrical equipment and powered industrial trucks.

9. Physical and chemical properties

For chemical and physico-chemical data see the Certificate of Standards (COS).

10. Stability and reactivity

Like any other powdered product, there is a risk of explosion in a confined cloud (combustible dust formation).

LEL g/m³	Pmax Bar	Kst bar.m/s	MIE mJ
30 - 125	6.3 - 8,9	24 - 121	1000 mJ (lactose monohydrate) 10 mJ (lactose monohydrate, micronized)
MIT °C	Smoulder °C	Dust Explosion class	
360-470	300-360	ST1	

LEL= Lower explosion limit; Pmax= Maximum explosion pressure; Kst=Maximum rate of pressure rise; MIE= Minimum ignition energy; MIT= Determination of the minimum ignition temperature; Smoulder= Smoulder temperature.

11. Toxicological information

No toxic effects are to be expected when the product is handled appropriately.

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12. Ecological information

No ecological problems are to be expected when the product is handled and used with due care and attention.

13. Disposal considerations

Products and Packaging

There are no uniform EC Regulations for the disposal of chemicals or residues. Chemical residues generally count as special waste. The disposal of the latter is regulated in the EC member countries through corresponding laws and regulations. We recommend that you contact either the authorities in charge or approved waste disposal companies which will advise you on how to dispose of special waste.

14. Transport information

Not subject to limitations due to transport regulations.

15. Regulatory information

Labeling according to applicable local legislation; Keep away from sources of ignition – No smoking.

16. Other information

Please refer to;
NFPA 654, *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids*, for safe handling

OSHA information on combustible dusts;

https://www.osha.gov/pls/publications/publication.athruz?pType=Industry&pID=250

ATEX Directive 2014/34/EU

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This statement substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name : Lorina Bisharat
Job title : Regulatory Affairs Manager
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

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