

MATERIAL SAFETY DATA SHEET

Brand names:	ARMOR PHARMA TM lactose monohydrate EXCIPRESS TM EXCIPURE TM
Product description:	Lactose Monohydrate Ph.Eur., USP/NF, JP

This document should be read in conjunction with the Ingredient Declaration and the Product Specification for the relevant product or product category.

1. Identification of the substance/preparation and of the company

Product name: ARMOR PHARMATM lactose monohydrate, EXCIPRESSTM, EXCIPURETM.

Manufacturer/Supplier identification : ARMOR PROTEINES SAS – 5 rue de Calouët – 22 600 LOUDEAC - FRANCE

2. Risk (Health Hazards)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008 amending Regulation (EC) No. 1907/2006.

This substance is not classified as dangerous according to Directive 67/548/EEC.

3. Composition/Information on ingredients

See Ingredient Declaration and the Product Specification

Cas No.	: 5989-81-1	Molecular weight	: 360,3 g/mol
EINECS No.	: 611-913-4	Formula	: C ₁₂ H ₂₂ O ₁₁ * H ₂ O

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. Hazards Fire-fighting measures

This product will burn. Suitable extinguishing media : water, powder, spray foam, CO₂.

6. Precautions

Avoid generation of dusts.

7. Handling and Storage

Keep in original, unopened packing and away from strongly odorous materials.

Storage: cf Technical Data sheet.

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.

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9. Physical and chemical properties

For chemical and physic-chemical data see the Product Specification.

10. Stability and reactivity

Like any other powdered product, there is a risk of explosion in a confined cloud.

LEL g/m ³	Pmax Bar	Kst bar.m/s	MIE mJ
30 – 125	6.3 – 8.9	24 - 121	1000
MIT °C	Smoulder °C	Dust Explosion class	
360-470	300 - 360	ST1	

MIE for micronized lactose is 10 mJ, other values lie within above indicated intervals. LEL= Lower Explosion Limity; Pmax = Maximum explosion pressure; Kst = Maximum rate of pressure rise; MIE = Minimum Ignition Energy; MIT = Minimum Ignition Temperature; Smoulder = Smoulder temperature

11. Toxicological information

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

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 diposal of chemicals and 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 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 transport regulations.

15. Regulatory information

Labeling according to EC directives; Keep away from sources of ignition – No smoking.

16. Other information

The information given in this sheet is provided to the best of our knowledge and experience in safety matters, however without any obligation and with any assumption of liability on our part.

Frédérique GREAULT
Pharmacist Quality Manager

