



SAFETY DATA SHEET

PHARMACEUTICAL LACTOSE MONOHYDRATE PH. EUR. USP / NF - JP

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	PHARMACEUTICAL LACTOSE MONOHYDRATE PH. EUR. USP / NF - JP
Product number	62444
Synonyms; trade names	ALPHATAB DC250, ALPHATAB DC550, ALPHATAB DC150 EP USP JP
REACH registration notes	This product is not classified as hazardous, the information in this datasheet is given for guidance only.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Food / Feed additive Pharmaceuticals
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1.3. Details of the supplier of the safety data sheet

Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com
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1.4. Emergency telephone number

Emergency telephone	SGS - +32 (0)3 575 55 55 (24h)
Sds No.	62444

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards	Not Classified
Health hazards	Not Classified
Environmental hazards	Not Classified

2.2. Label elements

Hazard statements	NC Not Classified
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2.3. Other hazards

This substance is not classified as PBT or vPvB according to current EU criteria.

SECTION 3: Composition/information on ingredients

3.1. Substances

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Composition comments The data shown are in accordance with the latest EC Directives.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Rinse nose and mouth with water. Get medical attention if any discomfort continues.

Ingestion Rinse mouth thoroughly with water. Do not induce vomiting unless under the direction of medical personnel. Give plenty of water to drink. Get medical attention if any discomfort continues.

Skin contact Remove affected person from source of contamination. After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water. Get medical attention if any discomfort continues.

Eye contact Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Get medical attention promptly if symptoms occur after washing.

4.2. Most important symptoms and effects, both acute and delayed

Eye contact Solid particles trapped behind the eyelid may cause abrasive damage.

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor Treat symptomatically. If in doubt, get medical attention promptly.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards Dust may form explosive mixture with air. When heated and in case of fire, toxic vapours/gases may be formed.

Hazardous combustion products Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours. Oxides of the following substances: Carbon.

5.3. Advice for firefighters

Special protective equipment for firefighters Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Provide adequate ventilation. Wear protective clothing as described in Section 8 of this safety data sheet. Follow precautions for safe handling described in this safety data sheet. Avoid inhalation of dust and contact with skin and eyes. Avoid generation and spreading of dust.

6.2. Environmental precautions

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Environmental precautions Do not discharge into drains or watercourses or onto the ground. Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Avoid generation and spreading of dust. Remove spillage with vacuum cleaner or collect with a shovel and broom, or similar. Collect and place in suitable waste disposal containers and seal securely. Label the containers containing waste and contaminated materials and remove from the area as soon as possible. Flush contaminated area with plenty of water.

6.4. Reference to other sections

Reference to other sections Wear protective clothing as described in Section 8 of this safety data sheet. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Provide adequate ventilation. Wear protective clothing as described in Section 8 of this safety data sheet. Follow precautions for safe handling described in this safety data sheet. Avoid inhalation of dust and contact with skin and eyes. Avoid handling which leads to dust formation. Avoid heat, flames and other sources of ignition.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in tightly-closed, original container in a dry, cool and well-ventilated place. Keep at temperature not exceeding 25°C.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

Ingredient comments No exposure limits known for ingredient(s).

8.2. Exposure controls

Protective equipment



Appropriate engineering controls

Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation or other engineering controls as the primary means to minimise worker exposure.

Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Dust-resistant, chemical splash goggles. Personal protective equipment for eye and face protection should comply with European Standard EN166.

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. To protect hands from chemicals, gloves should comply with European Standard EN374.

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Other skin and body protection	Wear appropriate clothing to prevent repeated or prolonged skin contact.
Hygiene measures	When using do not eat, drink or smoke. Wash at the end of each work shift and before eating, smoking and using the toilet. Remove contaminated clothing and protective equipment before entering eating areas. Eye wash facilities and emergency shower must be available when handling this product.
Respiratory protection	Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible. Protection against nuisance dust must be used when the airborne concentration exceeds 10 mg/m ³ . Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked. If ventilation is inadequate, suitable respiratory protection must be worn. Particulate filter, type P3. EN 136/140/141/145/143/149

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Powder.
Colour	White. to Slight. Yellow.
Odour	Characteristic.
Odour threshold	No information available.
pH	No information available.
Melting point	No information available.
Pour Point	No information available.
Freezing Point	No information available.
Initial boiling point and range	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Evaporation factor	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	Lower flammable/explosive limit: 125 g/m ³
Other flammability	No information available.
Vapour pressure	No information available.
Vapour density	No information available.
Relative density	No information available.
Bulk density	No information available.
Solubility(ies)	No information available.
Partition coefficient	No information available.
Auto-ignition temperature	No information available.
Decomposition Temperature	No information available.
Viscosity	No information available.

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Explosive properties No information available.

Explosive under the influence of a flame No information available.

Oxidising properties No information available.

9.2. Other information

Other information Not determined.

Refractive index No information available.

Particle size No information available.

Molecular weight No information available.

Volatility No information available.

Saturation concentration No information available.

Critical temperature No information available.

Volatile organic compound No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity There are no known reactivity hazards associated with this product.

10.2. Chemical stability

Stability Stable at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Dust may form explosive mixture with air.

10.4. Conditions to avoid

Conditions to avoid Avoid heat, flames and other sources of ignition. Static electricity and formation of sparks must be prevented. Keep at temperature not exceeding 25°C.

10.5. Incompatible materials

Materials to avoid No information available.

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours. Oxides of the following substances: Carbon.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Skin corrosion/irritation

Animal data No information available.

Serious eye damage/irritation

Serious eye damage/irritation No information available.

Respiratory sensitisation

Respiratory sensitisation No information available.

Skin sensitisation

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Skin sensitisation No information available.

Germ cell mutagenicity

Genotoxicity - in vitro No information available.

Carcinogenicity

Carcinogenicity No information available.

Reproductive toxicity

Reproductive toxicity - fertility No information available.

Specific target organ toxicity - single exposure

STOT - single exposure No information available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure No information available.

Aspiration hazard

Aspiration hazard No information available.

Inhalation Dust in high concentrations may irritate the respiratory system.

Ingestion Gastrointestinal symptoms, including upset stomach.

Skin contact Prolonged skin contact may cause redness and irritation.

Eye contact Solid particles trapped behind the eyelid may cause abrasive damage.

SECTION 12: Ecological information

Ecotoxicity The product is not expected to be hazardous to the environment. However, large or frequent spills may have hazardous effects on the environment.

12.1. Toxicity

Toxicity Not considered toxic to fish.

12.2. Persistence and degradability

Persistence and degradability The product is biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient No information available.

12.4. Mobility in soil

Mobility No information available.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This substance is not classified as PBT or vPvB according to current EU criteria.

12.6. Other adverse effects

Other adverse effects Not determined.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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General information	Waste should be treated as controlled waste. Do not puncture or incinerate, even when empty.
Disposal methods	Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

SECTION 14: Transport information

General	The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).
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14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78
and the IBC Code

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

EU legislation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended). Commission Regulation (EU) No 2015/830 of 28 May 2015.
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15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

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Abbreviations and acronyms used in the safety data sheet

ATE: Acute Toxicity Estimate.
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
 CAS: Chemical Abstracts Service.
 DNEL: Derived No Effect Level.
 IATA: International Air Transport Association.
 IMDG: International Maritime Dangerous Goods.
 Kow: Octanol-water partition coefficient.
 LC₅₀: Lethal Concentration to 50 % of a test population.
 LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).
 PBT: Persistent, Bioaccumulative and Toxic substance.
 PNEC: Predicted No Effect Concentration.
 REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
 RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.
 vPvB: Very Persistent and Very Bioaccumulative.
 IARC: International Agency for Research on Cancer.
 MARPOL 73/78: International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978.
 cATpE: Converted Acute Toxicity Point Estimate.
 BCF: Bioconcentration Factor.
 BOD: Biochemical Oxygen Demand.
 EC₅₀: 50% of maximal Effective Concentration.
 LOAEC: Lowest Observed Adverse Effect Concentration.
 LOAEL: Lowest Observed Adverse Effect Level.
 NOAEC: No Observed Adverse Effect Concentration.
 NOAEL: No Observed Adverse Effect Level.
 NOEC: No Observed Effect Concentration.
 LOEC: Lowest Observed Effect Concentration.
 DMEL: Derived Minimal Effect Level.
 EL50: Exposure Limit 50
 hPa: Hectopascal
 LL50: Lethal Loading fifty
 OECD: Organisation for Economic Co-operation and Development
 POW: Octanol-water partition coefficient
 SCBA: self-contained breathing apparatus
 STP: Sewage Treatment Plant
 VOC: Volatile Organic Compounds

Classification abbreviations and acronyms

Acute Tox. = Acute toxicity
 Aquatic Acute = Hazardous to the aquatic environment (acute)
 Aquatic Chronic = Hazardous to the aquatic environment (chronic)

Key literature references and sources for data

Supplier's information.

Revision comments

NOTE: Lines within the margin indicate significant changes from the previous revision.

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13/10/2022

Version number

2.000

Supersedes date

07/07/2021

SDS number

62444

PHARMACEUTICAL LACTOSE MONOHYDRATE PH. EUR. USP / NF - JP**SDS status**

Approved.

Signature

Lisa Bland

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