

## Material Safety Data Sheet

According to 91/155/EEC

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

Identification of the substance or preparation

LACTOSE Ph.Eur.: Tablettose 70, Tablettose 80, Tablettose 100, SorboLac 400, PrismaLac 40, CapsuLac 60, SpheroLac 100, GranuLac 140, GranuLac 70, GranuLac 200, GranuLac 230, SacheLac 80, InhaLac 70, InhaLac 120, InhaLac 230, FlowLac 100

Use of the substance/preparation

Used for pharmaceutical formulations, food, diatetics and technical formulation.

Company/undertaking identification

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SPECIMEN

### 2. Composition/information on ingredients

Generic name : Lactobiose, Milksugar, Lactose Monohydrate (Ph.Eur., USP/NF, JP)

Lactose EP is a 4-O-(β-D-Galactopyranosyl)-α-D-glucopyranose-Monohydrate

CAS-No.: 64044-51-5

MW: 360.32 g/mol

R-Phrases:

Content:

Molecular formula: C<sub>12</sub>H<sub>22</sub>O<sub>11</sub> · H<sub>2</sub>O

ELINCS-Index-No.: not listed

EINECS-No.: 200-559-2

no hazardous in sense of the guideline

99 - 101 %

Full text of R-Phrases: refer to section 15.

### 3. Hazards identification

#### 3.1 Adverse human health effect(s) and symptom(s)

May cause eye irritation.

May cause skin irritation.

May cause irritation of the digestive tract. Ingestion of large amounts may cause gastrointestinal irritation.

May cause respiratory tract irritation.

Avoid formation of dust. The use of this product is described at section 6 and 7.

Substance, combustible. Dust explosive, dust explosion class: ST 1.

#### 3.2 Adverse environmental effect(s):

Refer to section 12.

### 4. First-aid measures

#### 4.1 On inhalation:

Move affected person into fresh air, keep warm and allow to rest. In case of accident or if the person feels unwell, seek medical advice immediately (show safety data sheet where possible).

#### 4.2 On contact with the eyes:

On contact with the eyes, rinse immediately with plenty of water for at least 15 minutes, seek medical advice (show safety data sheet where possible).

#### 4.3 On contact with skin:

On contact with the skin, wash off immediately with water. In case of skin reactions, seek medical advice (show safety data sheet where possible).

#### 4. First-aid measures

##### 4.1 If swallowed:

Rinse mouth and drink 2-4 cupful of water.

In case of accident or if you feel unwell, seek medical advice immediately (show safety data sheet where possible).

#### 5. Fire-fighting measures

##### 5.1 Suitable extinguishing media:

Water spray jet, Foam, ABC-powder. Co-ordinate fire-fighting measures to the fire surroundings.

##### 5.2 Extinguishing media which must not be used for safety reasons:

unknown

##### 5.3 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:

Substances potentially set free in case of fire: Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>).

##### 5.4 Special protective equipment for firefighting:

Use breathing apparatus with independent air supply (isolated)

##### 5.5 Additional information:

Co-ordinate fire-fighting measures to the fire surroundings. Collect contaminated firefighting water separately.

#### 6. Accidental release measures

Refer to section 13. Use personal protective clothing like mentioned at section 8.

##### 6.1 Personal precautions:

Avoid dust formation. Use personal protective clothing. Avoid eye and skin contact. Keep away from sources of ignition.

Don't smoke. Ensure adequate ventilation. Take precautionary measures against electrostatic loading.

##### 6.2 Environmental precautions:

Contain spillage.

##### 6.3 Methods for cleaning up / taking up:

Clean contaminated floors and objects thoroughly observing environmental regulations. Treat recovered material as prescribed in:

Disposal considerations at section 13. avoid dust formation. Take precautionary measures against electrostatic loading.

#### 7. Handling and storage

##### 7.1 Handling

###### Hints for safe handling:

Refer to section 6.1

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid contact with eyes and skin. Avoid formation of dust. If local exhaust ventilation is impossible or insufficient, provide sufficient ventilation of the workplace. Take precautionary measures against electrostatic loading. Dust explosive, dust explosion class: ST 1. Keep away from sources of ignition - refrain from smoking.

##### 7.2 Storage

###### Technical measures and storage conditions:

Keep packaging tightly closed and store in a cool, dry place.

Suitable materials for container/equipment: common packaging for food.

Unsuitable materials for container/equipment: no data available.

###### Further information on storage conditions:

Refer to section 10.2

Keep packaging tightly closed and store in a cool, dry place.

#### 8. Exposure limitation and personal protective equipment

Substance	%	Occupational exposure limits:
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Name

Dust limit

3 mg/m<sup>3</sup> alveolar fraction

10 mg/m<sup>3</sup> respiratory fraction

##### Personal protection equipment

###### 8.1. Respiratory protection:

Respiratory protection necessary at: exposure limit excess.

Suitable respiratory protection apparatus : Particle filter (DIN EN 143).

###### 8.2 Hand protection:

Recommended:

Disposable gloves (EN 374).

###### 8.3 Eye protection:

Eye glasses with side protection.

###### 8.4 Protective clothing:

Protective clothing (e.g Safety shoes EN 344, long sleeved working clothes)

Additional information to hand protection: No tests were executed. The information is based on the statement of the manufacturer.



## 9. Physical and chemical properties

Physical state:	Solid Powder.
Colour:	white
Odour:	odourless
pH-value 10%:	4.0-6.5 (at 100 g/l water, 20 °C)
Physical state change (in °C):	Not determinable
Melting-point / Melting range:	202 °C (alpha-form, monohydrate)
Flash point (in °C):	n. d. a
Flammability:	class 2
Explosive properties:	Dust explosive
Lower explosion limit:	about 60-125 g/m <sup>3</sup> , depending on particle size (*)
Ignition temperature:	420-450 °C, depending on particle size (*)
Dust explosive class:	ST 1 (*)
Vapour pressure:	n. a.
Bulk density:	330-390 g/l (SorboLac 400) 450-550 g/l (PrismaLac 40, GranuLac 200, 230) 540-660 g/l (CapsuLac 60) 500-600 g/l (Tabletose 70, 80, 100) 550-650 g/l (GranuLac 140, FlowLac 100) 530-670 g/l (GranuLac 70, Sachelac 80) 670-770 g/l (SpheruLac 100)
Water solubility:	approx. 16.1 % (20 °C), freely soluble in water 50 °C
Partition coefficient n-octanol / water (log p OW):	n. a.

## 10. Stability and reactivity

### 10.1 Conditions to avoid:

Refer to section 7.

No hazardous decomposition products if stored and handled as prescribed.

Danger of dust explosion.

Take precautionary measures against electrostatic loading.

### 10.2 Materials to avoid:

Strong smelling material

### 10.3 Hazardous decomposition products:

No hazardous decomposition products if stored and handled as prescribed.

## 11. Toxicological information

### 11.1 Acute toxicity:

11.1.1 LD50 Rat oral (mg / kg):	>10g/kg (food)
11.1.2 LD50 Rat inhalative (mg/kg/4h):	n.d.a. (food)
11.1.3 LD50 Rat dermal (mg/kg):	n.d.a. (food)
11.1.4 to eye:	n.d.a. (food)

### 11.2 Subacute to chronic toxicity:

#### 11.2.1 Sensitisation:

contains traces of milk protein: inhalation of dust may lead to sensitisation in some allergic individuals (refer Section 7)

#### 11.2.2 Carcinogenic toxic effects:

n.d.a. (food)

#### 11.2.3 Mutagenic toxic effects:

n.d.a. (food)

#### 11.2.4 Reproductive toxic effects:

n.d.a. (food)

#### 11.2.5 Narcotic effects:

n.d.a. (food)

### 11.3 Other information:

This product is a food preparation.

This product contains milk protein, sensitisation in some allergic individuals may be occurred.

## 12. Ecological information

Water hazard class:

nwg = not water hazardous according to German VwVwS 1999 1.2d

Self-assessment:

No, KBwS

Information about elimination (persistence and degradation)

n. d. a. (food)

Behaviour in waste water treatment plants:

n. d. a. (food)

Aquatic toxicity:

n. d. a. (food)

Ecotoxicology:

n. d. a. (food)

Mobility:

n. d. a. (food)

Taking up and accumulation in organism:

n. d. a. (food)

(bioaccumulation potential)

n. d. a. (food)

Further ecological information:

n. d. a. (food)

Overall evaluation:

This product is used as food in the food industry.

### 13. Disposal considerations

#### 13.1 Disposal / Waste (product):

Dispose of in compliance with official regulations.

List of proposed waste codes/waste designations in accordance with EWC:

02 05 WASTES FROM THE DAIRY PRODUCTS INDUSTRY

02 05 99 wastes not otherwise specified

Landfill together with household waste, after coordination with waste management company.

#### 13.2 Packages:

Dispose of in compliance with official regulations.

Completely emptied packages may be recycled.

### 14. Transport information

Land transport (ADR/GGVS, RID/GGVE)

UN-No.

Class/Packing group:

Classification code:

Label:

Inland waterway craft/ Marine transport (IMDG)

GGVSee/IMDG-Code:

EmS-No.:

Marine Pollutant

Air transport ICAO/IATA

IATA:

Transport / Further information

No hazardous material as defined by the transport regulations (ADR/RID, IMDG-Code, ICAO-TI / IATA-DGR).

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### 15. Regulatory information

Hazard(ous) symbol(s) and indication(s) of danger for dangerous substances and preparations (67/548/EEC and 1999/45/EC):

Hazard(ous) symbol(s) and indication(s) of danger

For dangerous substances and preparations:

R-phrases:

none

S-phrases:

none

Classification according to VbF:

none

Other regulations, restrictions and prohibition

n.a.

regulations:

n.a.

General advices:

No hazardous material

Storage class according to VCI: 11

### 16. Other information

This information is based on our present knowledge.

Revised sections:

9

Further information:

Data references: BIA-Report (\*)

#### Legend:

n.a. = not applicable / n. d. a. = no data available

VbF = Verordnung über brennbare Flüssigkeiten

Water hazard class (WGK):

Nwg = not water hazardous, WGK1 = slightly water hazardous, WGK2 = water hazardous, WGK3 = extremely water hazardous

KBwS = Kommission Bewertung wassergefährlicher Stoffe, VwVwS = Verwaltungsvorschrift wassergefährdende Stoffe, EWC = European Waste Catalogue

This information is based on our present knowledge. It characterizes the product for appropriate safety precautions. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Existing legal obligations have to be fulfilled, according to the user's own responsibility.

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