



## Safety Data Sheet

### 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Code: 000928  
Product name: LACTOSE POWDER EP-USP

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

Intended use: pharmaceutical excipients

#### 1.3. Details of the supplier of the safety data sheet

Name: ACEF S.p.A.  
Full address: Via Umbria, 8/14  
District and Country: 29017 Fiorenzuola d'Arda PC  
Italia  
Tel. 0523/241911  
Fax 0523/241968

e-mail address of the competent person responsible for the Safety Data Sheet: [sicurezza@acef.it](mailto:sicurezza@acef.it)

#### 1.4. Emergency telephone number

For urgent inquiries refer to: Centro Antiveleni Milano Niguarda - Tel.02/66101029

### 2. Hazards identification

#### 2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

#### 2.2. Label elements

This product is not subject to hazard labeling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Pictograms: --

Warning: --

Hazard indication: --

Caution recommendations:

Label EC: 200-559-2

#### 2.3. Other hazards

Information not available

### 3. Composition/information on ingredients

#### 3.1. Substances

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions set forth in Directives 67/548/EEC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

#### 3.2. Mixtures

Information not relevant



## 4. First aid measures

### 4.1. Description of first aid measures

No harm to the staff authorised to use has been reported. However, in case of contact, inhalation or ingestion, the following general measures provided for a first aid shall be taken.

**INHALATION:** remove to open air. If respiration is difficult, administer artificial respiration and seek medical advice.

**INGESTION:** seek medical attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person.

**EYES and SKIN:** wash with plenty of water; if the irritation persists, seek medical advice.

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

No episodes of damage to health ascribable to the product have been reported.

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

Follow doctor's orders.

## 5. Firefighting measures

### 5.1. Extinguishing media

SUITABLE EXTINGUISHING MEDIA

The extinction equipment used should be of the conventional kind: carbon dioxide, foam, powder and nebulised water.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

None in particular.

### 5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

### 5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with ties around arms, legs and waist), work gloves (fireproof, cut proof and dielectric), a depressurised mask with facemask covering the whole of the operator's face or a self-respirator (self-protector) in the event of large quantities of fume.

## 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust. Use breathing equipment if powders are released into the air.

### 6.2. Environmental precautions

The product must not penetrate the sewer system, surface water, ground water and neighbouring areas.

### 6.3. Methods and material for containment and cleaning up

Use mechanical tools to collect leaked product and eliminate the remainder using jets of water. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

### 6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

## 7. Handling and storage

### 7.1. Precautions for safe handling

Do not smoke while handling and use.

### 7.2. Conditions for safe storage, including any incompatibilities

Store in a well ventilated place, keep far away from sources of heat, bright flames and sparks and other sources of ignition.



### 7.3. Specific end use(s)

Information not available

## 8. Exposure controls/personal protection

### 8.1. Control parameters

Information not relevant

**Information not available**

### 8.2. Exposure controls

Observance of safety measures used in handling chemical substances.

#### RESPIRATORY PROTECTION

None required.

#### EYE PROTECTION

None required.

#### HAND PROTECTION

None required.

#### SKIN PROTECTION

None required.

## 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance	powder
Colour	white
Odour	characteristic
Odour threshold	Not available
pH	4-5
Melting or freezing point	209 °C
Boiling point	Not available
Distillation range	Not available
Flash point	Not available
Evaporation Rate	Not available
Flammability of solids and gases	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Specific gravity	1 - 1,1
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available
Ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Reactive Properties	Not available

### 9.2. Other information

Molecular weight	360,31
VOC (Directive 1999/13/EC) :	0%

## 10. Stability and reactivity

Condition to avoid: avoid high temperature, moisture and direct light. Substances to avoid: oxygen , oxidizing substances. Hazardous decomposition products: when exposed to high temperature may produce hazardous decomposition products such as carbon monoxide and dioxide, smoke and/or nitrogen oxides and/or sulfur oxides.

### 10.1. Reactivity

Information not available

### 10.2. Chemical stability

Information not available



### 10.3. Possibility of hazardous reactions

Information not available

### 10.4. Conditions to avoid

Information not available

### 10.5. Incompatible materials

Information not available

### 10.6. Hazardous decomposition products

Information not available

## 11. Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity: LDL (ivn-dog): 1500 mg/Kg.

## 12. Ecological information

### 12.1. Toxicity

Information not available

### 12.2. Persistence and degradability

Information not available

### 12.3. Bioaccumulative potential

Information not available

### 12.4. Mobility in soil

Information not available

### 12.5. Results of PBT and vPvB assessment

Information not available

### 12.6. Other adverse effects

Information not available

## 13. Disposal considerations

### 13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Solid residues may be suitable for disposal in an authorised landfill site.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

## 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

## 15. Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso category None

Substances in Candidate List (Art. 59 REACH)  
None

Substances subject to authorisation (Annex XIV REACH)  
Information not available

Healthcare controls  
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**ACEF S.p.A.**  
**000928 - LACTOSE POWDER EP-USP**

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## 15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains

## 16. Other information

### GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atq. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. The Merck Index. - 10th Edition
8. Handling Chemical Safety
9. Niosh - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique (toxicological sheet)
11. Patty - Industrial Hygiene and Toxicology
12. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

### Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product .

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.