

# Safety data sheet

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BASF Safety data sheet  
Date / Revised: 31.03.2023  
Product: **Ludipress®**

Version: 1.0

(30034982/SDS\_GEN\_AR/EN)

Date of print 20.10.2025

## 1. Substance/preparation and company identification

### Ludipress®

Major Recommended Uses:

Use: pharmaceutical excipient

Company:

BASF Argentina S.A.  
Tucumán 1  
CP1049 Buenos Aires, ARGENTINA  
Telephone: +54 11 4317-9600  
Telefax number: +54 11 4317-9700  
E-mail address: ehs-ar@basf.com

Emergency information:

Telephone: 0800 444 9998/+55 12 3128-1590

## 2. Hazards Identification

### Classification of the substance or mixture

According to UN GHS criteria

No need for classification according to GHS criteria for this product.

### Label elements

According to UN GHS criteria

The product does not require a hazard warning label in accordance with GHS criteria.

### Other hazards

#### According to UN GHS criteria

##### Other Hazards (GHS):

Fine dust produced by abrasion can form explosive mixtures with air.

##### Assessment PBT / vPvB:

According to Annex XIII of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.. Self classification

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### 3. Composition/Information on Ingredients

#### Mixtures

Chemical nature

Preparation based on:

alpha-lactose-monohydrate (Content (W/W): 93 %)

crosslinked, 2-Pyrrolidinone, 1-ethenyl-, homopolymer (Content (W/W): 7 %)

Hazardous ingredients (GHS)

According to UN GHS criteria

No particular hazards known.

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### 4. First-aid measures

General advice:

Remove contaminated clothing.

If inhaled:

Keep patient calm, remove to fresh air.

On skin contact:

Wash thoroughly with soap and water

On contact with eyes:

Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion:

Rinse mouth and then drink 200-300 ml of water.

Note to physician:

Symptoms: (Further) symptoms and / or effects are not known so far

Treatment: Symptomatic treatment (decontamination, vital functions).

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## 5. Fire-fighting measures

Suitable extinguishing media:  
water spray, dry powder, foam, carbon dioxide

Unsuitable extinguishing media for safety reasons:  
water jet

Specific hazards:  
carbon oxides, nitrogen oxides, harmful vapours  
The substances/groups of substances mentioned can be released in case of fire. Dust explosion hazard.

Further information:  
Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.  
Cool endangered containers with water-spray.

Special protective equipment:  
Wear a self-contained breathing apparatus.

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## 6. Accidental release measures

Personal precautions, protective equipment and emergency measures

Personal precautions:  
Avoid dust formation. Use personal protective clothing. Information regarding personal protective measures, see section 8.

Environmental precautions:  
Do not discharge into drains/surface waters/groundwater.

Methods for cleaning up or taking up:  
For small amounts: Contain with dust binding material and dispose of.  
For large amounts: Sweep/shovel up.  
Dispose of absorbed material in accordance with regulations. Avoid raising dust.

Other relevant information: Dust can form an explosive mixture with air.

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## 7. Handling and storage

### Handling

Technical measures:  
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Avoid contact with the skin, eyes and clothing.

Fire and explosion protection:  
Avoid dust formation. The product is capable of dust explosion. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

Precautions/ Advice on safe handling:

Avoid dust formation. Provide exhaust ventilation if dust is formed.

Specific hygiene measures:

No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

Storage

Further information on storage conditions: Keep container tightly closed and dry; store in a cool place. Protect from the effects of light.

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## 8. Exposure controls and personal protection

Specific control parameters

Components with occupational exposure limits:

No substance specific occupational exposure limits known.

Personal protective equipment

Eye protection:

Safety glasses with side-shields (frame goggles) (e.g. EN 166)

Skin and body protection:

Body protection must be chosen based on level of activity and exposure.

Hand protection:

Wear chemical resistant protective gloves.

Respiratory protection:

Breathing protection if breathable aerosols/dust are formed. Particle filter with low efficiency for solid particles (e.g. EN 143 or 149, Type P1 or FFP1)

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## 9. Physical and chemical properties

State of matter: solid  
(20 °C, 1.013 hPa)

Form: granules

Colour: white

Odour: odourless

pH value: No data available.

Specific temperatures or temperature ranges at which changes in physical state occur

Melting point: > 210 °C

Boiling point: not applicable

Flash point: not applicable, the product is a solid

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Lower explosion limit:	For solids not relevant for classification and labelling.	
Upper explosion limit:	For solids not relevant for classification and labelling.	
Thermal decomposition:	approx. 146 °C Decomposes on heating.	
Self heating ability:	It is not a substance capable of spontaneous heating according to UN transport regulations class 4.2.	(VDI 2263, sheet 1, 1.4.1)
Explosion hazard:	Product is not explosive, however a dust explosion could result from an air / dust mixture.	
Fire promoting properties:	Based on its structural properties the product is not classified as oxidizing.	
Vapour pressure:	No data available.	
Relative vapour density (air):	negligible not applicable	
Density:	No information is available for the absolute density. Instead the bulk density was determined as a more relevant value.	
Bulk density:	350 - 450 kg/m <sup>3</sup>	
Relative density:	No data available.	
Solubility in water:	partly soluble	
Solubility (qualitative) solvent(s):	organic solvents insoluble	
Partitioning coefficient n-octanol/water (log Pow):	not applicable for mixtures	
Self-ignition temperature:	not applicable, the product is a solid	
Self ignition:	Based on its structural properties the product is not classified as self-igniting.	
Odour threshold limit value:	not applicable, odour not perceivable	
Evaporation rate:	The product is a non-volatile solid.	
Flammability:	not highly flammable	(VDI 2263, sheet 1, 1.1)
Viscosity, dynamic:	not applicable, the product is a solid	

Corrosion to metals: Corrosive effects to metal are not anticipated.

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## 10. Stability and reactivity

### Reactivity:

No hazardous reactions if stored and handled as prescribed/indicated.

### Chemical stability:

The product is stable if stored and handled as prescribed/indicated.

### Hazardous reactions:

The product may contain explosive fine dust or such dust may be produced by abrasion during transport or product transfer. No hazardous reactions if stored and handled as prescribed/indicated.

### Conditions to avoid:

See SDS section 7 - Handling and storage. Avoid dust formation. Avoid electro-static charge.

### Incompatible materials and substances:

atmospheric moisture, strong oxidizing agents

### Hazardous decomposition products:

No hazardous decomposition products if stored and handled as prescribed/indicated.

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## 11. Toxicological information

### Acute toxicity

#### Assessment of acute toxicity:

Virtually nontoxic after a single ingestion. Virtually nontoxic by inhalation.

*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*LD50 rat (oral): > 2.000 mg/kg (BASF-Test)*  
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*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*LC50 rat (by inhalation): > 5,2 mg/l 4 h (OECD Guideline 403)*  
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### Local effects

#### Assessment of irritating effects:

Not irritating to eyes and skin.

*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*Primary skin irritation rabbit: non-irritant (Draize test)*  
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*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*Eye irritation rabbit: non-irritant (Draize test)*  
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### **Assessment other acute effects**

Remarks: No data available.

### **Sensitization**

Assessment of sensitization:  
No data available.

### **Genetic toxicity**

Assessment of mutagenicity:  
No data was available concerning mutagenic activity.

### **Carcinogenicity**

Assessment of carcinogenicity:  
No data was available concerning carcinogenic activity.

### **Reproductive toxicity**

Assessment of reproduction toxicity:  
No data available.

### **Developmental toxicity**

Assessment of teratogenicity:  
No data was available concerning toxicity to development.

### **Repeated dose toxicity**

Assessment of repeated dose toxicity:  
No data available.

### **Aspiration Hazard**

Assessment of Aspiration Hazard:  
not applicable

### **Other relevant toxicity information**

The product has not been tested. The statement has been derived from the properties of the individual components.

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## **12. Ecological information**

Possible environmental effects, behaviour and fate

## Ecotoxicity

Assessment of aquatic toxicity:

There is a high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations. The product has not been tested. The statement has been derived from the properties of the individual components.

*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*Assessment of aquatic toxicity:*

*There is a high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.*

*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*Toxicity to fish:*

*LC50 (96 h) > 10.000 mg/l, Leuciscus idus (DIN 38412 Part 15, static)*

*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*Microorganisms/Effect on activated sludge:*

*EC20 (0,5 h) > 1.995 mg/l, activated sludge, industrial (OECD Guideline 209, aerobic)*

## Persistence and degradability

Assessment biodegradation and elimination (H<sub>2</sub>O):

Poorly eliminated from water. The product has not been tested. The statement has been derived from the properties of the individual components.

*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*Assessment biodegradation and elimination (H<sub>2</sub>O):*

*Poorly eliminated from water.*

*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*Elimination information:*

*< 10 % DOC reduction (15 d) (OECD Guideline 302 B) (aerobic, activated sludge, industrial) Poorly eliminated from water.*

## Bioaccumulation

Assessment bioaccumulation potential:

The product has not been tested.

*Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked*

*Bioaccumulation potential:*

*Based on its structural properties, the polymer is not biologically available. Accumulation in organisms is not to be expected.*



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## Mobility

Assessment transport between environmental compartments:  
not determined

## Additional information

Other ecotoxicological advice:  
The product has not been tested. The statements on ecotoxicology have been derived from the properties of the individual components.

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## 13. Disposal considerations

Methods for safe and environmentally preferred disposal  
Product: Observe national and local legal requirements.

Product residues: Observe national and local legal requirements.

Contaminated packaging:  
Uncontaminated packaging can be re-used.  
Packs that cannot be cleaned should be disposed of in the same manner as the contents.

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## 14. Transport information

### Land transport

Not classified as a dangerous good under transport regulations

### Waterway Transport

IMDG

Not classified as a dangerous good under transport regulations

### Air transport

IATA/ICAO

Not classified as a dangerous good under transport regulations

### Additional Information

Classification of land transport generated according to the criteria of Resolution 64:2022.

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## 15. Regulatory information

### **Other regulations**

If other regulatory information applies that is not already provided elsewhere in this safety data sheet, then it is described in this subsection.

This SDS (Safety Data Sheet) is in accordance with the requirement of the Resolution 801/15 of the SRT

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## **16. Other information**

Any other intended applications should be discussed with the manufacturer. Corresponding occupational protection measurements must be followed.

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Vertical lines in the left hand margin indicate an amendment from the previous version.

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. The data do not describe the product's properties (product specification). Neither should any agreed property nor the suitability of the product for any specific purpose be deduced from the data contained in the safety data sheet. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.