

# Safety data sheet

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BASF safety data sheet. This is a translation of the country-specific safety data sheet into a language other than that required by law. This document does not replace the safety data sheet provided according to Regulation (EC) No 1907/2006.

Date / Revised: 16.09.2025

Version: 4.0

Date / Previous version: 24.04.2023

Previous version: 3.0

Product: **Ludipress®**

(ID no. 30034982/SDS\_GEN\_EU/EN)

Date of print 21.10.2025

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

### 1.1. Product identifier

**Ludipress®**

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

Relevant identified uses: pharmaceutical excipient

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

Company:

BASF SE

67056 Ludwigshafen

GERMANY

Operating Division Nutrition and Health

Telephone: +49 621 60-48434

E-mail address: EN-global-safety-data@basf.com

### 1.4. Emergency telephone number

International emergency number:

Telephone: +49 180 2273-112

## SECTION 2: Hazards Identification

### 2.1. Classification of the substance or mixture

For the classification of the mixture the following methods have been applied: extrapolation on the concentration levels of the hazardous substances, on basis of test results and after evaluation of experts. The methodologies used are mentioned at the respective test results.

According to Regulation (EC) No 1272/2008 [CLP]

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

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## 2.2. Label elements

According to Regulation (EC) No 1272/2008 [CLP]

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

## 2.3. Other hazards

According to Regulation (EC) No 1272/2008 [CLP]

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

The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

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## SECTION 3: Composition/Information on Ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Chemical nature

Preparation based on:

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

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

Regulatory relevant ingredients

No particular hazards known.

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## SECTION 4: First-Aid Measures

### 4.1. Description of first aid measures

Remove contaminated clothing.

If inhaled:

Keep patient calm, remove to fresh air.

On skin contact:

Wash thoroughly with soap and water

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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.

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

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

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

Treatment: Symptomatic treatment (decontamination, vital functions).

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### **SECTION 5: Fire-Fighting Measures**

#### **5.1. Extinguishing media**

Suitable extinguishing media:

water spray, dry powder, foam, carbon dioxide

Unsuitable extinguishing media for safety reasons:

water jet

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

Endangering substances: carbon oxides, nitrogen oxides, harmful vapours

Advice: The substances/groups of substances mentioned can be released in case of fire. Dust explosion hazard.

#### **5.3. Advice for fire-fighters**

Special protective equipment:

Wear a self-contained breathing apparatus.

Further information:

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Cool endangered containers with water-spray.

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### **SECTION 6: Accidental Release Measures**

Dust can form an explosive mixture with air.

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

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

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## 6.2. Environmental precautions

Do not discharge into drains/surface waters/groundwater.

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

## 6.4. Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

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# SECTION 7: Handling and Storage

## 7.1. Precautions for safe handling

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

Protection against fire and explosion:

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.

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

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

## 7.3. Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

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# SECTION 8: Exposure Controls/Personal Protection

## 8.1. Control parameters

Components with occupational exposure limits

5989-81-1: alpha-lactose-monohydrate

9003-39-8: 2-Pyrrolidinone, 1-ethenyl-, homopolymer

9003-39-8: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked

## 8.2. Exposure controls

Personal protective equipment

Respiratory protection:

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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)

Hand protection:

Wear chemical resistant protective gloves.

Eye protection:

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

Body protection:

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

#### General safety and hygiene 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. 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.

## **SECTION 9: Physical and Chemical Properties**

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

State of matter:	solid	
Form:	granules	
Colour:	white	
Odour:	odourless	
Odour threshold:	not applicable, odour not perceivable	
Melting point:	> 210 °C	
Boiling point:	not applicable	
Flammability:	not highly flammable	(VDI 2263, sheet 1, 1.1 (May 1990))
Lower explosion limit:	For solids not relevant for classification and labelling.	
Upper explosion limit:	For solids not relevant for classification and labelling.	
Flash point:	not applicable, the product is a solid	
Auto-ignition temperature:	not applicable, the product is a solid	
Thermal decomposition:	approx. 215 °C (DSC (DIN 51007))	
pH value:	No data available.	
Viscosity, dynamic:	not applicable, the product is a solid	
Solubility in water:	partly soluble	

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Solubility (qualitative) solvent(s): organic solvents  
insoluble

Partitioning coefficient n-octanol/water (log Kow):  
not applicable for mixtures

Vapour pressure:  
negligible

Density:  
No information is available for the absolute density. Instead the bulk density was determined as a more relevant value.

Relative vapour density (air):  
not applicable

#### Particle characteristics

Particle size distribution: typically > 100 µm (D50, Volumetric Distribution, ISO 13320-1)

## **9.2. Other information**

### **Information with regard to physical hazard classes**

#### Explosives

Explosion hazard: Product is not explosive, however a dust explosion could result from an air / dust mixture.

#### Oxidizing properties

Fire promoting properties: Based on its structural properties the product is not classified as oxidizing.

#### Self-heating substances and mixtures

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 (May 1990))

#### Corrosion to metals

Corrosive effects to metal are not anticipated.

### **Other safety characteristics**

Bulk density: 350 - 450 kg/m<sup>3</sup>

SAPT-Temperature: Study scientifically not justified.

Evaporation rate: The product is a non-volatile solid.

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## SECTION 10: Stability and Reactivity

### 10.1. Reactivity

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

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

### 10.2. Chemical stability

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

### 10.3. Possibility of 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.

### 10.4. Conditions to avoid

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

### 10.5. Incompatible materials

Substances to avoid:  
atmospheric moisture, strong oxidizing agents

### 10.6. Hazardous decomposition products

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

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## SECTION 11: Toxicological Information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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*

*Experimental/calculated data:*

*LD50 rat (oral): > 2,000 mg/kg (BASF-Test)*

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

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*Experimental/calculated data:*

*LC50 rat (by inhalation): > 5.2 mg/l 4 h (OECD Guideline 403)*

Irritation

Assessment of irritating effects:

Not irritating to eyes and skin.

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

*Experimental/calculated data:*

*Skin corrosion/irritation*

*rabbit: non-irritant (Draize test)*

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

*Experimental/calculated data:*

*Serious eye damage/irritation*

*rabbit: non-irritant (Draize test)*

Respiratory/Skin sensitization

Assessment of sensitization:

No data available.

Germ cell mutagenicity

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.

Specific target organ toxicity (single exposure)

Remarks: No data available.

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity:

No data available.



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#### Aspiration hazard

not applicable

#### Interactive effects

No data available.

### **11.2. Information on other hazards**

#### Endocrine disrupting properties

Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

#### Other information

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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## **SECTION 12: Ecological Information**

### **12.1. Toxicity**

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.*

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*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)*

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

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*Microorganisms/Effect on activated sludge:*

*EC20 (0.5 h) > 1,995 mg/l, activated sludge, industrial (OECD Guideline 209, aerobic)*

## 12.2. 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.*

## 12.3. Bioaccumulative potential

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.*

## 12.4. Mobility in soil

Assessment transport between environmental compartments:

Adsorption in soil: not determined

## 12.5. Results of PBT and vPvB assessment

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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## 12.6. Endocrine disrupting properties

Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

## 12.7. Other adverse effects

The product does not contain substances that are listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

### 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.

## SECTION 13: Disposal Considerations

### 13.1. Waste treatment methods

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.

## SECTION 14: Transport Information

### Land transport

ADR

	Not classified as a dangerous good under transport regulations
UN number or ID number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

RID

	Not classified as a dangerous good under transport regulations
UN number or ID number:	Not applicable
UN proper shipping name:	Not applicable

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Transport hazard class(es): Not applicable  
Packing group: Not applicable  
Environmental hazards: Not applicable  
Special precautions for user: None known

### **Inland waterway transport**

ADN

Not classified as a dangerous good under transport regulations  
UN number or ID number: Not applicable  
UN proper shipping name: Not applicable  
Transport hazard class(es): Not applicable  
Packing group: Not applicable  
Environmental hazards: Not applicable  
Special precautions for user: None known

### **Transport in inland waterway vessel**

Not evaluated

### **Sea transport**

IMDG

Not classified as a dangerous good under transport regulations  
UN number or ID number: Not applicable  
UN proper shipping name: Not applicable  
Transport hazard class(es): Not applicable  
Packing group: Not applicable  
Environmental hazards: Not applicable  
Special precautions for user: None known

### **Air transport**

IATA/ICAO

Not classified as a dangerous good under transport regulations  
UN number or ID number: Not applicable  
UN proper shipping name: Not applicable  
Transport hazard class(es): Not applicable  
Packing group: Not applicable  
Environmental hazards: Not applicable  
Special precautions for user: None known

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#### **14.1. UN number or ID number**

See corresponding entries for "UN number or ID number" for the respective regulations in the tables above.

#### **14.2. UN proper shipping name**

See corresponding entries for "UN proper shipping name" for the respective regulations in the tables above.

#### **14.3. Transport hazard class(es)**

See corresponding entries for "Transport hazard class(es)" for the respective regulations in the tables above.

#### **14.4. Packing group**

See corresponding entries for "Packing group" for the respective regulations in the tables above.

#### **14.5. Environmental hazards**

See corresponding entries for "Environmental hazards" for the respective regulations in the tables above.

#### **14.6. Special precautions for user**

See corresponding entries for "Special precautions for user" for the respective regulations in the tables above.

#### **14.7. Maritime transport in bulk according to IMO instruments**

Maritime transport in bulk is not intended.

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### **SECTION 15: Regulatory Information**

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

##### Prohibitions, Restrictions and Authorizations

Annex XVII of Regulation (EC) No 1907/2006: Number on List: 78

The synthetic polymer microparticles supplied are subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

Synthetic Polymer Microparticle content: 3 - 4 %

Generic information on the identity of the SPM polymers contained (polymer classes): Polymers of vinyl acetate or of other vinyl esters; other vinyl polymers

Directive 2012/18/EU - Control of Major Accident Hazards involving dangerous substances (EU):

Listed in above regulation: no

Classification applies for standard conditions of temperature and pressure.

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## 15.2. Chemical Safety Assessment

Chemical Safety Assessment not required

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## SECTION 16: Other Information

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

### Abbreviations

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road.  
ADN = The European Agreement concerning the International Carriage of Dangerous Goods by Inland waterways. ATE = Acute Toxicity Estimates. CAO = Cargo Aircraft Only. CAS = Chemical Abstract Service. CLP = Classification, Labelling and Packaging of substances and mixtures. DIN = German national organization for standardization. DNEL = Derived No Effect Level. EC50 = Effective concentration median for 50% of the population. EC = European Community. EN = European Standards. IARC = International Agency for Research on Cancer. IATA = International Air Transport Association. IBC-Code = Intermediate Bulk Container code. IMDG = International Maritime Dangerous Goods Code. ISO = International Organization for Standardization. STEL = Short-Term Exposure Limit. LC50 = Lethal concentration median for 50% of the population. LD50 = Lethal dose median for 50% of the population. TLV = Threshold Limit Value. MARPOL = The International Convention for the Prevention of Pollution from Ships. NEN = Dutch Norm. NOEC = No Observed Effect Concentration. OEL = Occupational Exposure Limit. OECD = Organization for Economic Cooperation and Development. PBT = Persistent, Bioaccumulative and Toxic. PNEC = Predicted No Effect Level. PPM = Parts per million. RID = The European Agreement concerning the International Carriage of Dangerous Goods by Rail. TWA = Time Weight Average. UN-number = UN number at transport. vPvB = very Persistent and very Bioaccumulative.

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. This safety data sheet is neither a Certificate of Analysis (CoA) nor technical data sheet and shall not be mistaken for a specification agreement. Identified uses in this safety data sheet do neither represent an agreement on the corresponding contractual quality of the substance/mixture nor a contractually designated use. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

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