

Safety data sheet

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Safety data sheet according to UN GHS 4th rev.

Date / Revised: 16.01.2023

Version: 2.0

Product: **Ludipress®**

(ID no. 30034982/SDS_GEN_ZA/EN)

Date of print 12.10.2025

1. Identification

Product identifier

Ludipress®

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

Relevant identified uses: pharmaceutical excipient

Details of the supplier of the safety data sheet

Company:

Emergency telephone number

National emergency number:

+27 11 203 2420

International emergency number:

Telephone: +49 180 2273-112

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

Globally Harmonized System (GHS)

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

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Other hazardsAccording to UN GHS criteria

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

3. Composition/Information on Ingredients**Substances**

Not applicable

MixturesChemical 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.

4. First-Aid Measures**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

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.

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

| Treatment: Symptomatic treatment (decontamination, vital functions).

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5. Fire-Fighting Measures

Extinguishing media

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

Unsuitable extinguishing media for safety reasons:
water jet

Special hazards arising from the substance or mixture

carbon oxides, nitrogen oxides, harmful vapours

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

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.

6. Accidental Release Measures

Dust can form an explosive mixture with air.

Personal precautions, protective equipment and emergency procedures

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 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.

7. Handling and Storage

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.

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.

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.

8. Exposure Controls/Personal Protection**Control parameters**Components with occupational exposure limits

No substance specific occupational exposure limits known.

Exposure controlsPersonal protective equipment

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)

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.

9. Physical and Chemical Properties**Information on basic physical and chemical properties**

Form:	granules
Colour:	white
Odour:	odourless
Odour threshold:	not applicable, odour not perceivable
pH value:	No data available.
Melting point:	> 210 °C
Boiling point:	not applicable
Flash point:	not applicable, the product is a solid

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Evaporation rate:	The product is a non-volatile solid.	
Flammability:	not highly flammable	(VDI 2263, sheet 1, 1.1)
Lower explosion limit:	For solids not relevant for classification and labelling.	
Upper explosion limit:	For solids not relevant for classification and labelling.	
Ignition temperature:	not applicable, the product is a solid	
Vapour pressure:	negligible	
Relative vapour density (air):	not applicable	
Solubility in water:	partly soluble	
Solubility (qualitative) solvent(s):	organic solvents insoluble	
Partitioning coefficient n-octanol/water (log Kow):	not applicable for mixtures	
Self ignition:	Based on its structural properties the product is not classified as self-igniting.	
Thermal decomposition:	approx. 146 °C (internal method) Decomposes on heating.	
Viscosity, dynamic:	not applicable, the product is a solid	
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.	

Other information

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)
Bulk density:	350 - 450 kg/m ³	

10. Stability and Reactivity**Reactivity**

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

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

Chemical stability

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

Possibility of hazardous reactions

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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

Substances to avoid:
atmospheric moisture, strong oxidizing agents

Hazardous decomposition products

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

11. Toxicological Information**Information on toxicological effects**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)

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

| *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

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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.

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.

12. Ecological Information

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:

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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 (H₂O):

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 (H₂O):*

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.

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.

Mobility in soil

Assessment transport between environmental compartments:

Adsorption in soil: not determined

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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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.

13. Disposal Considerations

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.

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
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

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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

Maritime transport in bulk according to IMO instruments

Maritime transport in bulk is not intended.

15. Regulatory Information

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

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

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16. Other Information

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

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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