

Safety Data Sheet

Ludipress®

Revision date : 2025/07/18

Version: 2.0

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(30034982/SDS_GEN_CR/EN)

1. Identification

Product identifier used on the label

Ludipress®

Recommended use of the chemical and restriction on use

Recommended use*: pharmaceutical excipient

Unsuitable for use: Not intended for sale to or use by the general public.

* The "Recommended use" identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

Company:

BASF de Costa Rica S.A.
Building Epic Corporate Center, First Floor,
Trejos Montealegre, Escazu
San Jose, COSTA RICA

Telephone: +506 2201-1990

Emergency telephone number

24 Hour Emergency Response Information

CHEMTREC 1-703-527-3887

Centro Nacional de Control de Intoxicaciones: (506 2223-1028/222-0122/911)

Other means of identification

Synonyms:

Preparation based on alpha-lactose-monohydrate, crosslinked 2-Pyrrolidinone, 1-ethenyl-, homopolymer

2. Hazards Identification

According to Executive Decree No. 40457-S

Classification of the product

Combustible Dust

Combustible Dust (1)

Combustible Dust

Label elements

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Signal Word:
Warning

Hazard Statement:
May form combustible dust concentration in air.

Hazards not otherwise classified

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

3. Composition / Information on Ingredients

According to Executive Decree No. 40457-S

Under the referenced regulation, this product does not contain any components classified for health hazards above the relevant cut off value.

4. First-Aid Measures

Description of first aid measures

General advice:
Remove contaminated clothing.

If inhaled:
Keep patient calm, remove to fresh air.

If on skin:
Wash thoroughly with soap and water

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

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

Most important symptoms and effects, both acute and delayed

Symptoms: No data available.

Indication of any immediate medical attention and special treatment needed

Note to physician

Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Extinguishing media

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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

Hazards during fire-fighting:
Dust explosion hazard.

Advice for fire-fighters

Protective equipment for fire-fighting:
Wear a self-contained breathing apparatus.

Further information:

Dusty conditions may ignite explosively in the presence of an ignition source causing flash fire.

6. Accidental release measures

Further accidental release measures:

Avoid dispersal of dust in the air (e.g. by clearing dusty surfaces with compressed air). Avoid the formation and build-up of dust - danger of dust explosion. Dust in sufficient concentration can result in an explosive mixture in air. Handle to minimize dusting and eliminate open flame and other sources of ignition.

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.

Nonsparking tools should be used.

7. Handling and Storage

Precautions for safe handling

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

Protection against fire and explosion:

Avoid whirling up the material/product because of the danger of dust explosion. Dust in sufficient concentration can result in an explosive mixture in air. Handle to minimize dusting and eliminate open flame and other sources of ignition. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when

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subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids (2013 Edition) for safe handling.

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.

8. Exposure Controls/Personal Protection

No substance specific occupational exposure limits known.

Advice on system design:

Ensure adequate ventilation. Local exhaust ventilation preferred. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection:

Breathing protection if dusts are formed. Wear a NIOSH-certified (or equivalent) particulate respirator.

Hand protection:

Chemical resistant protective gloves

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. Avoid inhalation of dust. 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

Physical state:	solid
Form:	granules
Odour:	odourless
Odour threshold:	not applicable, odour not perceivable
Colour:	white
pH value:	No data available.
Melting point:	> 210 °C
Freezing point:	No data available.
Boiling point:	not applicable

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Flash point:	not applicable, the product is a solid	(VDI 2263, sheet 1, 1.1 (May 1990))
Flammability:	not highly flammable	
Lower explosion limit:	For solids not relevant for classification and labelling.	
Upper explosion limit:	For solids not relevant for classification and labelling.	
Autoignition:	not applicable, the product is a solid	
Vapour pressure:	negligible	
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 ³	
Relative vapour density:	not applicable	
Partitioning coefficient n-octanol/water (log Pow):	not applicable for mixtures	
Self-ignition temperature:	Based on its structural properties the product is not classified as self-igniting.	
Thermal decomposition:	approx. 215 °C (DSC (DIN 51007))	
Viscosity, dynamic:	not applicable, the product is a solid	
Viscosity, kinematic:	not applicable	
Solubility in water:	partly soluble	
Solubility (qualitative):	insoluble	
	solvent(s): organic solvents,	
Molecular weight:	not applicable	
Evaporation rate:	The product is a non-volatile solid.	

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.

Oxidizing properties:

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

Chemical stability

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

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.

Conditions to avoid

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

Incompatible materials

atmospheric moisture, strong oxidizing agents

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Hazardous decomposition products

Decomposition products:

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

Thermal decomposition:

approx. 215 °C (DSC (DIN 51007))

11. Toxicological information

Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity

Assessment of acute toxicity: Virtually nontoxic after a single ingestion. Virtually nontoxic by inhalation.

Oral

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

Type of value: LD50

Species: rat

Value: > 2,000 mg/kg (BASF-Test)

Inhalation

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

Type of value: LC50

Species: rat

Value: > 5.2 mg/l (OECD Guideline 403)

Exposure time: 4 h

Dermal

No data available.

Assessment other acute effects

No data available.

Irritation / corrosion

Assessment of irritating effects: Not irritating to eyes and skin.

Skin

No data available.

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

Species: rabbit

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Result: non-irritant
Method: Draize test

Eye

No data available.

Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, cross-linked
Species: rabbit
Result: non-irritant
Method: Draize test

Sensitization

Assessment of sensitization: No data available.

Aspiration Hazard

not applicable

Chronic Toxicity/Effects

Repeated dose toxicity

Assessment of repeated dose toxicity: 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.

Teratogenicity

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

Other Information

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

12. Ecological Information

Toxicity

Aquatic 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.

Aquatic toxicity

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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.

Toxicity to fish

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

LC50 (96 h) > 10,000 mg/l, Leuciscus idus (DIN 38412 Part 15, static)

Assessment of terrestrial toxicity

No data available.

Microorganisms/Effect on activated sludge

Toxicity to microorganisms

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

OECD Guideline 209 aerobic

activated sludge, industrial/EC20 (0.5 h): > 1,995 mg/l

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.

Assessment biodegradation and elimination (H₂O)

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

Poorly eliminated from water.

Elimination information

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

< 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.

Bioaccumulation potential

No data available.

Bioaccumulation potential

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

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
not determined

Additional information

Add. remarks environm. fate & pathway:
No data available.

Other ecotoxicological advice:
The product has not been tested.

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

13. Disposal considerations

Waste disposal of substance:

Observe national and local legal requirements.

Container disposal:

Dispose of in accordance with national, state and local regulations.

14. Transport Information

Land transport

TDG

Not classified as a dangerous good under transport regulations

Sea transport

IMDG

Not classified as a dangerous good under transport regulations

Air transport

IATA/ICAO

Not classified as a dangerous good under transport regulations

15. Regulatory Information

Federal Regulations

Not applicable

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NFPA Hazard codes:

Health: 0

Fire: 1

Reactivity: 0

Special:

16. Other Information

SDS Prepared by:

BASF NA Product Regulations

SDS Prepared on: 2025/07/18

We support worldwide Responsible Care® initiatives. We value the health and safety of our employees, customers, suppliers and neighbors, and the protection of the environment. Our commitment to Responsible Care is integral to conducting our business and operating our facilities in a safe and environmentally responsible fashion, supporting our customers and suppliers in ensuring the safe and environmentally sound handling of our products, and minimizing the impact of our operations on society and the environment during production, storage, transport, use and disposal of our products.

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This information is considered accurate but is not exhaustive and shall only be used as a guideline based on current knowledge of the chemical substance or mixture. Safety precautions suitable for the product must be applied.

Date / Revised: 2025/07/18

Date / Previous version: 2019/07/31

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Previous version: 1.0

END OF DATA SHEET