

Safety data sheet

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BASF Safety data sheet
Date / Revised: 08.03.2023
Product: **Ludipress®**

Version: 2.0

(30034982/SDS_GEN_NZ/EN)

Date of print: 21.10.2025

1. Substance/preparation and manufacturer/supplier identification

Product name:
Ludipress®

Use: pharmaceutical excipient

Manufacturer/supplier:
BASF New Zealand Ltd.
5E City Works Depot
77 Cook Street
Auckland Central, Auckland 1010
NEW ZEALAND
Telephone: +64 9 255-4300
Telefax number: +64 9 255-4307

Emergency information:
National Poisons Centre: 0800 764 766
BASF Emergency Advice Number: 0800 944 955 (24 hour advice in an emergency only)
BASF Emergency Advice Number: +61 3 8855 6666 (If calling from outside New Zealand)

2. Hazard identification

Classification of the substance and mixture:
| No need for classification according to GHS criteria for this product.

Label elements and precautionary statement:

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

Other hazards which do not result in classification:
Fine dust produced by abrasion can form explosive mixtures with air.

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3. Composition/information on ingredients

Chemical nature

Substance nature: mixture

Preparation based on:

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

crosslinked

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

No particular hazards known.

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).

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.

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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

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.

Additional information: Dust can form an explosive mixture with air.

7. Handling and Storage

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.

Storage

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 and personal protection

Components with occupational exposure limits

| No substance specific occupational exposure limits known.

Personal 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

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	
Evaporation rate:	The product is a non-volatile solid.	
Flammability (solid/gas):	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	
Thermal decomposition:	approx. 146 °C Decomposes on heating.	(internal method)
Self ignition:	Based on its structural properties the product is not classified as self-igniting.	

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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:	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 (air):	not applicable	
Solubility in water:	partly soluble	
Solubility (qualitative) solvent(s):	organic solvents insoluble	
Partitioning coefficient n-octanol/water (log Pow):	not applicable for mixtures	
Viscosity, dynamic:	not applicable, the product is a solid	

10. Stability and Reactivity

Conditions to avoid:

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

Thermal decomposition: approx. 146 °C (internal method)
Decomposes on heating.

Substances to avoid:

atmospheric moisture, strong oxidizing agents

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

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.

Hazardous decomposition products:

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

Chemical stability:

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

Reactivity:

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

11. Toxicological Information

Routes of exposure

Assessment of acute toxicity

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

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

Acute oral toxicity

Experimental/calculated data:

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

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

Acute inhalation toxicity

Experimental/calculated data:

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

Symptoms

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

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.

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

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.

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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)

| 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)

Mobility

Assessment transport between environmental compartments:
not determined

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

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Elimination information:

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

Bioaccumulation 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.

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

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

Domestic transport:

	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

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
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

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.

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| A certified handler is not required for the handling of this substance.
| Tracking requirements do not apply to this substance.

16. Other Information

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

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. 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.