

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 14.05.2025

Version number 7.0 (replaces version 6.0)

Revision: 13.05.2025

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

1.1 Product identifier

Trade name: VitaFast® Chicken Pancreatin**Article number:** P2002

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

No further relevant information available.

Application of the substance / the preparation: In vitro

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

R-Biopharm AG

An der neuen Bergstraße 17

D-64297 Darmstadt

Further information obtainable from: e-mail: info@r-biopharm.de

1.4 Emergency telephone number:

CHEMTREC (worldwide): +1 703-741-5970 / 1-800-424-9300

For additional worldwide local emergency numbers refer to section 16.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

GHS08 health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms GHS08**Signal word** Danger**Hazard-determining components of labelling:**

γ-Glutamyl-Hydrolase

Hazard statements

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P284 [In case of inadequate ventilation] wear respiratory protection.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment**PBT:** Not applicable.**vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture: consisting of the following components.

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Dangerous components:

9074-87-7	γ-Glutamyl-Hydrolase	2.5 – 5%
	⚠ Resp. Sens. 1, H334	
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	

Additional information: For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures****4.1 Description of first aid measures****After inhalation:** Supply fresh air; consult doctor in case of complaints.**After skin contact:** Immediately wash with water and soap and rinse thoroughly.**After eye contact:** Rinse opened eye for several minutes under running water.**After swallowing:** If symptoms persist consult doctor.**4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.**5.2 Special hazards arising from the substance or mixture**

No further relevant information available.

5.3 Advice for firefighters**Protective equipment:** No special measures required.**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective clothing.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.**6.3 Methods and material for containment and cleaning up:**

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Open and handle receptacle with care.

No special precautions are necessary if used correctly.

Information about fire - and explosion protection: No special measures required.**7.2 Conditions for safe storage, including any incompatibilities****Storage:****Requirements to be met by storerooms and receptacles:** No special requirements.**Information about storage in one common storage facility:** Not required.

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Further information about storage conditions: None.**7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Appropriate engineering controls No further data; see section 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Hand protection



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the permanent contact gloves made of the following materials are suitable:

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.11 mm

Value for the permeation: Level ≤ 480

As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.11 mm

Value for the permeation: Level ≤ 480

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Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties**General Information**

Physical state	Solid
Colour:	Grey
Odour:	Characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	Undetermined.
Boiling point or initial boiling point and boiling range	Undetermined.
Flammability	Not determined.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Decomposition temperature:	Not determined.
pH	Not applicable.
Viscosity:	
Kinematic viscosity	Not applicable.
Dynamic:	Not applicable.
Solubility	
water:	Insoluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not applicable.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
Particle characteristics	See section 3.

9.2 Other information

Appearance:	
Form:	Solid
Important information on protection of health and environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	
Solids content:	100.0 %
Change in condition	
Evaporation rate	Not applicable.

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Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

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

Acute toxicity Based on available data, the classification criteria are not met.

Primary irritant effect:

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

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11.2 Information on other hazards**Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 Toxicity**Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** No further relevant information available.**12.3 Bioaccumulative potential** No further relevant information available.**12.4 Mobility in soil** No further relevant information available.**12.5 Results of PBT and vPvB assessment****PBT:** Not applicable.**vPvB:** Not applicable.**12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects**Additional ecological information:****General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

13.1 Waste treatment methods**Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

Uncleaned packaging:**Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN number or ID number

ADR, ADN, IMDG, IATA

Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA

Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class

Void

14.4 Packing group

ADR, IMDG, IATA

Void

14.5 Environmental hazards:**Marine pollutant:**

No

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14.6 Special precautions for user	Not applicable.
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
Transport/Additional information:	Not dangerous according to the above specifications.
UN "Model Regulation":	Void

SECTION 15: Regulatory information

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

National regulations:

Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Department issuing SDS: QS 0049-6151-8102-0

Contact: QS 0049-6151-8102-0

Worldwide local emergency numbers

Argentina Spanish Local (City) Buenos Aires Americas 54-1159839431

Australia English Local (City) Sydney Oceania 61-290372994

Austria German Local (City) Vienna Europe 43-13649237

Belgium French Local (City) Brussels Europe 32-28083237

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Brazil Portuguese Local (City) Rio De Janeiro Americas 55-2139581449
 Brazil Portuguese Local (City) Sao Paulo Americas 55-1143491359
 Brazil - Toll Free Portuguese Toll free Mobile-Enabled Americas 0800 892 0479
 Bulgaria Bulgarian Local (City) Plovdiv Europe 359-32570104
 Cayman Islands English Local (National) Americas 345-749-8392
 Chile Spanish Local (City) Santiago Americas 56 2 2581 4934
 China Mandarin Local (National) Asia 4001-204937
 Colombia Spanish Toll Free Americas 01800-710-2151
 Costa Rica Spanish Local (National) Americas 506-40003869
 Croatia Croatian Local (City) Zagreb Europe 385-17776920
 Czech Republic Czech Local (City) Prague Europe 420-228880039
 Denmark Danish Local (National) Europe 45-69918573
 Dominican Republic Spanish Local (City) Santo Domingo Americas (829) 956-7588
 El Salvador Spanish Local (City) San Salvador Americas 503 2136 7633
 Estonia Estonian Local (National) Europe 372-6681294
 Finland Finnish Local (City) Helsinki Europe 358-942419014
 France French National Europe 33-975181407
 Germany German Local (City) Frankfurt Europe 49-69643508409 0800-181-7059
 Greece Greek Local (City) Athens Europe 30-2111768478
 Grenada English Local (City) St George Americas 1 (473) 230-0165
 Guinea French Americas 224 660 71 03 00
 Hong Kong Toll Free Asia 800-968-793
 Hungary Hungarian Local (City) Budapest Europe 36-18088425
 Iceland Icelandic Local (City) Reykjavik Europe 354 539 0655
 India Hindi, Bengali, English Asia 000-800-100-7141
 Indonesia Indonesian Toll Free Asia 001-803-017-9114
 Ireland English Local (City) Dublin Europe 353-19014670
 Israel Hebrew Local (City) Tel Aviv Asia 972-37630639
 Italy Italian Local (City) Milan Europe 39-0245557031 800-789-767
 Japan Japanese Local (City) Tokyo Asia 81-345209637
 Latvia Latvian Lettish Local (City) Riga Europe 371-66165504
 Lithuania Lithuanian Local (City) Vilnius Europe 370-52140238
 Luxembourg French and German Europe 352-20202416
 Macedonia Macedonian Local (City) Skopje Europe 389 2 551 7456
 Malaysia Malay Local (City) Kuala Lumpur Asia 60-39212579 41-800-815-308
 Mexico Spanish Americas 01-800-681-9531
 Netherlands Dutch Europe 31-858880596
 New Zealand English Local (City) Auckland Oceania 64-98010034
 Nigeria Hausa Local (City) Lagos Europe 234 1 227 8883
 Panama Spanish Local (National) Americas 507-8322475
 Peru Spanish Local (City) Lima Americas 51-17071295
 Philippines Tagalog Local (City) Manila Asia 1-800-1-116-1020
 Poland Polish Local (City) Warsaw Europe 48-223988029
 Portugal Portuguese Local (National) Europe 351-308801773
 Romania Romanian Local (National) Europe 40-37-6300026
 Russia Russian Toll Free Mobile-Enabled Asia 8-800-100-6346
 Saudi Arabia Arabic and English CHEMTREC DID Only Asia 966-8111095861
 Singapore English and Mandarin Asia 65-31581349 or 800-101-2201
 Slovakia Slovak Local (City) Bratislava Europe 421-233057972
 Slovenia Slovenian Local (City) Ljubljana Europe 38-618888016
 South Africa English Toll Free Africa 0-800-983-611
 South Korea Korean Toll Free Asia 003-0813-2549 and 080-822-1374
 Spain Spanish Local (City) Barcelona Europe 34-931768545 and 900-868538
 Sweden Swedish Local (City) Stockholm Europe 46-852503403
 Switzerland German and French and Italian Zurich Europe 41-435082011
 Taiwan Mandarin Local (City) Taipei Asia 886-2-7741-4207 and 00801-14-8954
 Thailand Thai Toll Free Asia 01-800-13-203-9987

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Trinidad and Tobago English Local (National) Americas 1-868-224-5716

Turkey Turkish Local (City) Istanbul Europe 90-212-7055340

Ukraine Ukrainian Europe 380-947101374

United Kingdom English Local (City) London Europe 44-870-8200418 and 44-2038073798

Date of previous version: 16.08.2023**Version number of previous version:** 6.0**Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Resp. Sens. 1: Respiratory sensitisation – Category 1

*** Data compared to the previous version altered.**