

Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Product name **RENZYME PCR4**

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

Intended use **Additive for paper mill**

Identified Uses	Industrial	Professional	Consumer
Sizing agent	✓	-	-
Uses Advised Against			
Any use not included among those recommended			

1.3. Details of the supplier of the safety data sheet

Name **N.C.R. BIOCHEMICAL S.p.A.**
Full address **Via dei Carpentieri, 8-Zona Industriale il Prato**
District and Country **40050 Castello d'Argile (BO) Italia**
Tel. **+39 051 6869611 Lun-Ven 8.30-13.00/14.00-16.30**
Fax **+39 051 6869617**
e-mail address of the competent person responsible for the Safety Data Sheet **regulatory@ncr-biochemical.com**

1.4. Emergency telephone number

For urgent inquiries refer to **Italy:**
CAV Ospedale Niguarda Ca' Granda - Milano 02 66101029
CAV Azienda Ospedaliera Papa Giovanni XXII - Bergamo 800 883300
CAV Centro Nazionale di Informazione Tossicologica - Pavia 0382 24444
CAV Az. Osp. Careggi - Firenze 055 7947819
CAV Policlinico Gemelli - Roma 06 3054343
CAV Policlinico Umberto I - Roma 06 49978000
CAV Osp. Pediatrico Bambino Gesù - Roma 06 68593726
CAV Az. Osp. Cardarelli - Napoli 081 7472870
CAV Az. Osp. Univ. Foggia - Foggia 800183459

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to (EU) Regulation 2020/878.

Hazard classification and indication: --

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:
EUH210 Safety data sheet available on request.
EUH208 Contains: Cellulase
May produce an allergic reaction.

SECTION 2. Hazards identification ... / >>

Precautionary statements:

P280

Wear protective gloves/ protective clothing / eye protection / face protection.

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
Cellulase		
CAS	9012-54-8	$0,5 \leq x < 1$
EC	232-734-4	Resp. Sens. 1 H334
INDEX	647-002-00-3	
REACH Reg.	01-2119949289-21-XXXX	

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

Specific information on symptoms and effects caused by the product are unknown.

Cellulase

It may cause allergic respiratory reactions.

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

Cellulase

Symptomatic treatment.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

Cellulase

Unsuitable extinguishing media: Water jet.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

SECTION 5. Firefighting measures ... / >>

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use breathing equipment if fumes or powders are released into the air. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Cellulase									
Predicted no-effect concentration - PNEC									
Normal value in fresh water					0,0237	mg/l			
Normal value in marine water					0,00237	mg/l			
Normal value for water, intermittent release					0,237	mg/l			
Normal value of STP microorganisms					65	mg/l			
Normal value for the terrestrial compartment					0,00376	mg/kg			
Health - Derived no-effect level - DNEL / DMEL									
Route of exposure	Effects on consumers			Chronic	Chronic	Effects on workers		Chronic	Chronic
	Acute	Acute				Acute	Acute		
	local	systemic		local	systemic	local	systemic	local	systemic
Inhalation				0,000015				0,00006	
				mg/m3				mg/m3	

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

8.2. Exposure controls

SECTION 8. Exposure controls/personal protection ... / >>

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	amber	
Odour	light	
Odour threshold	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	> 100 °C	
Flammability	not applicable because the product is liquid	
Lower explosive limit	Not applicable	
Upper explosive limit	Not applicable	
Flash point	> 93 °C	Method:ASTM D93
Auto-ignition temperature	Not determined	
Decomposition temperature	Not determined	
pH	4,5 ÷ 5,5	Method:ITL 70 Temperature: 25 °C
Kinematic viscosity	< 50 cP	Method:ITL 66
Solubility	soluble in water	Method:ITL 73
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	1,018 ± 0,05 g/cm3	Method:ITL 15 B Temperature: 20 °C
Relative vapour density	Not determined	
Particle characteristics	Not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Explosive properties not applicable because it does

SECTION 9. Physical and chemical properties ... / >>

Oxidising properties

not contain any explosives
functional groups
not applicable because it does
not contain any oxidizing
functional groups

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:

Not classified (no significant component)

ATE (Oral) of the mixture:

Not classified (no significant component)

ATE (Dermal) of the mixture:

Not classified (no significant component)

Cellulase

LD50 (Oral):

LC50 (Inhalation mists/powders):

> 2880 mg/kg Rat, according to Annex to Commission Directive 92/69/EEC,
reliability 1

> 4,86 mg/l/4h Rat, according to OECD Guideline 403, reliability 1

SKIN CORROSION / IRRITATION

SECTION 11. Toxicological information ... / >>

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

May produce an allergic reaction.

Contains:

Cellulase

Respiratory sensitization

Cellulase

It may cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

Skin sensitization

Information not available

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Adverse effects on sexual function and fertility

Information not available

Adverse effects on development of the offspring

Information not available

Effects on or via lactation

Information not available

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Target organs

Information not available

Route of exposure

Information not available

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Target organs

Information not available

Route of exposure

Information not available

SECTION 11. Toxicological information ... / >>

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Cellulase	
LC50 - for Fish	> 100 mg/l/96h Oncorhynchus mykiss, semi-static, according to OECD Guideline 203, reliability 1
EC50 - for Crustacea	> 100 mg/l/48h Daphnia magna, static, according to OECD Guideline 202, reliability 1
EC50 - for Algae / Aquatic Plants	> 100 mg/l/72h Pseudokirchneriella subcapitata, static, according to OECD Guideline 201, reliability 1
Chronic NOEC for Fish	45,5 mg/l/4d Oncorhynchus mykiss, semi-static, according to OECD Guideline 203, reliability 1
Chronic NOEC for Crustacea	100 mg/l/2d Daphnia magna, static, according to OECD Guideline 202, reliability 1
Chronic NOEC for Algae / Aquatic Plants	52,1 mg/l/3d Pseudokirchneriella subcapitata, static, according to OECD Guideline 201, reliability 1

12.2. Persistence and degradability

Cellulase	
Rapidly degradable	60%, 5d, OCSE 301F

12.3. Bioaccumulative potential

Cellulase	
Partition coefficient: n-octanol/water	-1,3 (20 °C)

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 15. Regulatory information ... / >>

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Resp. Sens. 1	Respiratory sensitization, category 1
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
EUH210	Safety data sheet available on request.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety

SECTION 16. Other information ... / >>

- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:

The following sections were modified:

01 / 02 / 04 / 06 / 07 / 09 / 11 / 12 / 15 / 16.