Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Product name **RENZYME AS**

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

Intended use **Enzyme preparation**

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 **Headquarter Via dei Carpentieri, 8 - Zona Industriale il Prato**
District and Country **40050 Castello d'Argile (BO)**
Italia
Tel. +39 051 6869611 Mon-Fri 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.it**

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 classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Respiratory sensitization, category 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2. Label elements

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

Hazard pictograms:

SECTION 2. Hazards identification ... / >>

Signal words: Danger

Hazard statements:

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
EUH208 Contains: 1,2-benzisothiazol-3(2H)-one
May produce an allergic reaction.

Precautionary statements:

P261 Avoid breathing dust, fume, gas, mist, vapours, spray.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P304+P340 IF INHALED: remove person to fresh air and keep comfortable for breathing.

Contains: Amylase, α-

Product not intended for uses provided for by Dir. 2004/42/CE.

2.3. Other hazards

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

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
Amylase, α-		
CAS *9000-90-2*	1 ≤ x < 3	**Resp. Sens. 1 H334**
EC *232-565-6*		
INDEX *647-015-00-4*		
Reg. no. *01-2119938627-26-XXXX*		
1,2-benzisothiazol-3(2H)-one		
CAS *2634-33-5*	0 ≤ x < 0,05	**Acute Tox. 2 H330, Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Acute 1 H400 M=1, Aquatic Chronic 2 H411**
EC *220-120-9*		
INDEX *613-088-00-6*		
Reg. no. *EXEMPTED – Art. 15 (2) of REACH regulation*		

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

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

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

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

Information not available

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.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products.

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

Individual precautions: use personal protective clothing.
Environmental precautions: Contain polluted water and firefighting water. Do not empty into drains, surface waters or ground water.
Cleaning and collection: In case of large leaks, mechanically aspirate the product. In case of small leak, collect with suitable absorbent materials and dispose of the collected material according to the regulations in force.

6.1. Personal precautions, protective equipment and emergency procedures

Information not available

6.2. Environmental precautions

Information not available

6.3. Methods and material for containment and cleaning up

Information not available

6.4. Reference to other sections

Information not available

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)

See the exposure scenarios attached to this safety datasheet.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Amylase, α-								
Predicted no-effect concentration - PNEC								
Normal value in fresh water						0,00525	mg/l	
Normal value in marine water						0,00052	mg/l	
Normal value of STP microorganisms						65	mg/l	
Normal value for the terrestrial compartment						0,001	mg/kg	
Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation							0,000060 mg/m3	

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

8.2. Exposure controls

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.
When choosing risk management measures and operating conditions, consult the exposure scenarios attached.
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 B 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.
For information on controlling environmental exposure, see the exposure scenarios attached to this safety datasheet.

Respiratory protection: in case of insufficient ventilation, wear an approved particulate filter respirator P3, used in accordance with the traditions of the manufacturer.
Eye protection: safety glasses with side shields. Skin protection: lughe clothing with sleeves. Wear rubber or neoprene protective gloves nitrile according to EN 374-3. Penetration time scheduled> 4 hours

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	dense liquid	
Colour	amber	
Odour	characteristic	
Odour threshold	Not determined	

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

pH		5,5	Method:ITL 70 Remark:Range ± 1,0 Temperature:25 °C
Melting point / freezing point		-5 °C	Method:ITL 71
Initial boiling point	>	100 °C	
Boiling range		Not available	
Flash point	>	100 °C	Method:ASTM D93
Evaporation Rate		Not determined	
Flammability of solids and gases		not applicable because the product is liquid	
Lower inflammability limit		Not available	
Upper inflammability limit		Not available	
Lower explosive limit		Not applicable	
Upper explosive limit		Not applicable	
Vapour pressure		Not determined	
Vapour density		Not determined	
Relative density		1,25 ± 0,05 g/ml	Method:ITL 15 B
Solubility		soluble in water	Method:ITL 73
Partition coefficient: n-octanol/water		Not determined	
Auto-ignition temperature		Not applicable	
Decomposition temperature		Not determined	
Viscosity		Not determined	
Explosive properties		not applicable because it does not contain any explosives functional groups	
Oxidising properties		not applicable because it does not contain any oxidizing functional groups	

9.2. Other information

Information not available

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.

Avoid prolonged storage at extreme temperatures, below 0 ° C or exceeding 35 ° C

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 toxicological effects

SECTION 11. Toxicological information ... / >>

Amylase, α-
Unless otherwise specified in the following paragraphs, for the involved substance toxicological data in the following list are considered not available: acute toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT - single exposure, STOT - repeated exposure, aspiration hazard.

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

Amylase, α-
NOAEL (oral): >= 1 320 mg/kg bw/day
Oral repeated administration of the substance to rats was well-tolerated and did not produce any toxicologically significant changes (according to OECD Guideline 408, reliability 1).

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:	Not classified (no significant component)
LD50 (Oral) of the mixture:	Not classified (no significant component)
LD50 (Dermal) of the mixture:	Not classified (no significant component)

1,2-benzisothiazol-3(2H)-one

LD50 (Oral)	490 mg/kg Rat, equivalent or similar to OECD Guideline 401, reliability 1
LD50 (Dermal)	> 2000 mg/kg Rat, according to OECD Guideline 402, reliability 2
LC50 (Inhalation)	1,6 mg/l/4h calculated at the concentration of 20%

Amylase, α-

LD50 (Oral)	> 2000 mg/kg bw OECD TG 401, 420

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

Amylase, α-
Based on available data, the classification criteria are not met.
During tests in rabbits according to OECD Guideline 404 (reliability 1) the substance caused completely reversible effects at 48 or 72 hours after termination of exposure.

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

Amylase, α-
Based on available data, the classification criteria are not met.
During tests in rabbits according to OECD Guideline 405 (reliability 1) the substance caused completely reversible mild effects at 48 or 72 hours after termination of exposure.

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the respiratory system
May produce an allergic reaction.
Contains:
1,2-benzisothiazol-3(2H)-one

Respiratory sensitization
Amylase, α-
Active enzymes regardless of the catalytic activities are potential respiratory sensitisers (occupational data).

GERM CELL MUTAGENICITY

SECTION 11. Toxicological information ... / >>

Does not meet the classification criteria for this hazard class

Amylase, α-
No indication of mutagenic effects in bacterial and mammalian cell tests according to OECD Guidelines 471 and 476, reliability 1.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

No specific data are available for this product. Handle it according to good working practices. Avoid littering. Do not contaminate soil and waterways. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation. Please take all the proper measures to reduce harmful effects on aquifers.

12.1. Toxicity

1,2-benzisothiazol-3(2H)-one	
LC50 - for Fish	2,15 mg/l/96h Cyprinodon variegatus, EPA 540/9-85-006, reliability 1
EC50 - for Crustacea	2,9 mg/l/48h Daphnia magna, according to OECD Guideline 202, reliability 1
EC50 - for Algae / Aquatic Plants	0,0403 mg/l/72h Pseudokirchneriella subcapitata, according to OECD Guideline 201, reliability 1
Chronic NOEC for Algae / Aquatic Plants	0,11 mg/l Pseuriella subcapitata, according to OECD Guideline 201, reliability 1
Amylase, α-	
LC50 - for Fish	58,3 mg/l/96h Oncorhynchus mykiss, according to OECD Guideline 203, reliability 1
EC50 - for Crustacea	31,7 mg/l/48h OECD TG 202
EC50 - for Algae / Aquatic Plants	> 5,2 mg/l/72h Desmodesmus subspicatus, according to OECD Guideline 201, reliability 1

12.2. Persistence and degradability

1,2-benzisothiazol-3(2H)-one	
Rapidly degradable	
Amylase, α-	
Rapidly degradable	OECD 301

12.3. Bioaccumulative potential

1,2-benzisothiazol-3(2H)-one	
Partition coefficient: n-octanol/water	0,7 Log Kow OECD 117, S 324
BCF	6,95 - OECD 305, S 2243
Amylase, α-	
Partition coefficient: n-octanol/water	< 0 mg/l OECD 301F

12.4. Mobility in soil

Information not available

SECTION 12. Ecological information ... / >>

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 greater than 0,1%.

12.6. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
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 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
Product
Point 3

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None

Substances subject to the Rotterdam Convention:
None

SECTION 15. Regulatory information ... / >>

Substances subject to the Stockholm Convention:
None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

German regulation on the classification of substances hazardous to water (AwSV, vom 18. April 2017)
WGK 1: Low hazard to waters

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:

Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 4	Acute toxicity, category 4
Eye Dam. 1	Serious eye damage, category 1
Skin Irrit. 2	Skin irritation, category 2
Resp. Sens. 1	Respiratory sensitization, category 1
Skin Sens. 1	Skin sensitization, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
H330	Fatal if inhaled.
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H315	Causes skin irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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 NUMBER: 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: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average 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

SECTION 16. Other information ... / >>

3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament4. Regulation (EU) 2015/830 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) 2018/1480 (XIII Atp. CLP)
16. Regulation (EU) 2019/521 (XII Atp. CLP)

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

Product's classification is based on the calculation methods set out in Annex I of the CLP Regulation, unless otherwise indicated in sections 11 and 12.
The data for evaluation of chemical-physical properties are reported in section 9.

Changes to previous review:
The following sections were modified:
01 / 02 / 03 / 04 / 06 / 07 / 08 / 09 / 11 / 12 / 15 / Exposure Scenarios.

Exposure Scenarios

Substance	Amylase, α-
Scenario Title	SE_Alfa-amilasi
Revision nr.	1
File	EN_SEALFAAMILASI_1.pdf