Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878

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

1.1. Product identifier

Code: **2203454**
Product name **DIGESTION REAGENT**

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

Intended use **Reagent for microbiology**

1.3. Details of the supplier of the safety data sheet

Name **BIOLIFE ITALIANA S.R.L.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia
Tel. 0039 02 252091

e-mail address of the competent person responsible for the Safety Data Sheet **mktg@biolifeitaliana.it**

1.4. Emergency telephone number

For urgent inquiries refer to **NHS111in England: 111**
NHS24in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647

In an emergency, if the patient has collapsed or is not breathing properly, call 999

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 2020/878.
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:

Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.

2.2. Label elements

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

Hazard pictograms:

Signal words: Warning

Hazard statements:

H319 Causes serious eye irritation.
H315 Causes skin irritation.

Precautionary statements:

SECTION 2. Hazards identification ... / >>

P280	Wear protective gloves / eye protection / face protection.
P337+P313	If eye irritation persists: Get medical advice / attention.
P264	Wash . . . thoroughly after handling.

2.3. Other hazards

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

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

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification		x = Conc. %	Classification (EC) 1272/2008 (CLP)
SODIUM HYDROXIDE			
INDEX	*011-002-00-6*	1,5 ≤ x < 2	**Met. Corr. 1 H290, Skin Corr. 1A H314, Eye Dam. 1 H318**
EC	*215-185-5*		**Skin Corr. 1B H314: ≥ 2% - < 5%, Skin Corr. 1C H314: ≥ 2% - < 5%, Skin Irrit. 2 H315: ≥ 0,5% - < 2%, Eye Dam. 1 H318: ≥ 2%, Eye Irrit. 2 H319: ≥ 0,5% - < 2%**
CAS	*1310-73-2*		

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

In case of doubt or in the presence of symptoms contact a doctor and show him this document.
In case of more severe symptoms, ask for immediate medical aid.
EYES: Remove, if present, contact lenses if the situation allows you to do so easily. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. Get medical advice/attention.
SKIN: Take off contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical advice. Avoid further contact with contaminated clothing.
INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Do not give anything by mouth to an unconscious person. Get medical advice/attention.
INHALATION: Remove victim to fresh air, away from the accident scene. In the event of respiratory symptoms (coughing, wheezing, breathing difficulty, asthma) keep the victim in a comfortable position for breathing. If necessary administer oxygen. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.

Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.

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

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

DELAYED EFFECTS: Based on the information currently available, there are no known cases of delayed effects following exposure to this product.

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

If eye irritation persists: Get medical advice / attention.

Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

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

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. 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

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. 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

Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapours or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. 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

Regulatory references:

ESP	España	Límites de exposición profesional para agentes químicos en España 2024
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en FranceDécret n° 2021-1849 du 28 décembre 2021
GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ ''σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιγόνους παράγοντες κατά την εργασία''»
HRV	Hrvatska	PRAVILNIK O IZMJENAMA I DOPUNAMA PRAVILNIKA O ZAŠTITI RADNIKA OD IZLOŽENOSTI OPASNIM KEMIKALIJAMA NA RADU, GRANIČNIM VRIJEDNOSTIMA IZLOŽENOSTI I BIOLOŠKIM GRANIČNIM VRIJEDNOSTIMA
NOR	Norge	Forskrift om endring i forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier), 21. 10. april 2024 kl. 13.55
POL	Polska	ROZPORZĄDZENIE MINISTRA RODZINY, PRACY I POLITYKI SPOŁECZNEJ z dnia 24 czerwca 2024 r. zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
SWE	Sverige	Arbetsmiljöverkets föreskrifter och allmänna råd (AFS 2023:14) om gränsvärden för luftvägsexponering i arbetsmiljön
SVN	Slovenija	Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti rakotvornim, mutagenim ali reprotoksičnim snovem pri delu. Ljubljana, četrtek 4. 4. 2024
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
	ACGIH	ACGIH 2025

SODIUM HYDROXIDE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
VLA	ESP			2		
VLEP	FRA	2				
TLV	GRC	2		2		
GVI/KGVI	HRV			2		
TLV	NOR	2				
NDS/NDSCh	POL	0,5		1		
NGV/KGV	SWE	1		2		INHAL
MV	SVN	2		2		INHAL
WEL	GBR			2		
ACGIH				2 (C)		

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			1 mg/m3				1 mg/m3	

Legend:
(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

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.
Provide an emergency shower with face and eye wash station.
HAND PROTECTION
Protect hands with category III work gloves.
The following should be considered when choosing work glove material (see standard EN 374): compatibility, degradation, permeability time.
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.

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

SKIN PROTECTION
Wear category II 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 ISO 16321).
RESPIRATORY PROTECTION
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. 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).
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		transparent		
Odour		not available		
Melting point / freezing point		not available		
Initial boiling point		not available		
Flammability		not available		
Lower explosive limit		not available		
Upper explosive limit		not available		
Flash point	>	60	°C	
Auto-ignition temperature		not available		
Decomposition temperature		not available		
pH		12,97		Temperature: 25 °C
Kinematic viscosity		not available		
Solubility		not available		
Partition coefficient: n-octanol/water		not available		
Vapour pressure		not available		
Density and/or relative density		1,02		
Relative vapour density		not available		
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

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

SECTION 10. Stability and reactivity ... / >>

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.

SODIUM HYDROXIDE
Avoid exposure to: air,moisture,sources of heat.

10.5. Incompatible materials

SODIUM HYDROXIDE
Incompatible with: strong acids,ammonia,zinc,lead,aluminium,water,flammable liquids.

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)

SODIUM HYDROXIDE

LD50 (Dermal):	1350 mg/kg Rat
LD50 (Oral):	1350 mg/kg Rat

SKIN CORROSION / IRRITATION

Causes skin irritation

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

SECTION 11. Toxicological information ... / >>

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

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

Information not available

12.2. Persistence and degradability

SODIUM HYDROXIDE
Solubility in water > 10000 mg/l
Degradability: information not available

12.3. Bioaccumulative potential

Information not available

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 ≥ 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. 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.

SECTION 13. Disposal considerations ... / >>

The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.
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 or ID 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. Maritime transport in bulk according to IMO instruments

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/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
Product
Point 3
Contained substance
Point 75

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors
not applicable

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

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:
None

SECTION 15. Regulatory information ... / >>

Substances subject to the Rotterdam Convention:
None

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.

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:

Met. Corr. 1	Substance or mixture corrosive to metals, category 1
Skin Corr. 1A	Skin corrosion, category 1A
Skin Corr. 1B	Skin corrosion, category 1B
Skin Corr. 1C	Skin corrosion, category 1C
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.

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
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- 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
- vPvM: Very persistent and very mobile
- 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) 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)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
23. Delegated Regulation (UE) 2023/707
24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
25. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
26. Delegated Regulation (UE) 2024/197 (XXI Atp. CLP)
27. Delegated Regulation (UE) 2024/2564 (XXII 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.

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 / 03 / 04 / 08 / 09 / 11 / 13 / 16.