

According to Regulation 2020/878 concerning REACH.

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

1.1 Product identifier

BioPorto Diagnostics A/S ELISA kits identified by the following catalogue numbers and product names:

Human NGAL ELISA, KIT 036RUO Mouse NGAL ELISA, KIT 042 Dog NGAL ELISA, KIT 043 Pig NGAL ELISA, KIT 044 Monkey NGAL ELISA, KIT 045 Rat NGAL ELISA, KIT 046

This SDS is according to Regulation 2020/878 concerning REACH.

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

The BioPorto Diagnostics A/S ELISA kits are intended for in vitro determination of specific biomarkers in appropriate matrices. For specific use please consult the relevant kit IFU. For research use only.

1.3 Details of the supplier of the SDS



BioPorto Diagnostics A/S Tuborg Havnevej 15, st. DK-2900 Hellerup Denmark
 Phone:
 +45 4529 0000

 Fax:
 +45 4529 0001

 Email:
 info@bioporto.com

 Web:
 www.bioporto.com

1.4 Emergency phone number

Europe: 112

2. Hazards identification

2.1 Classification of the substance or mixture

The products are kits consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section 2.2 Label elements contains the resulting labeling for the kit.

2.2 Label elements

Labeling (REGULATION (EC) No 1272/2008)

Hazard pictogram:



Signal word: Warning

Hazard statements

H317 May cause an allergic skin reaction.

Prevention

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves.

Response

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.



According to Regulation 2020/878 concerning REACH.

Disposal

P501 Dispose of contents/container to an approved waste disposal plant.

2.3 Other hazards

See section 3.

3. Composition/information on ingredients

3.1 Substances

Classification (REGULATION (EC) No 1272/2008)

Skin sensitization, Category 1

H317 May cause an allergic skin reaction

Components

For explanation of abbreviations see section 16.

Chemical name	CAS-No EC-No Index-No Registration number	Classification	Concentration (% w/w)	
2-methyl-2H-isothiazol-3-one	2682-20-4 220-239-6 613-326-00-9 01-2120764690-50	Acute Tox. 3; H301 Acute Tox. 2, H330 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin sens. 1A; H335 (Respiratory system) Aquatic acute 1; H400 Aquatic chronic 1; H410 EUH071	>=0.025 - < 0.1	
		M-factor (acute aquatic toxicity): 10. M-factor (chronic aquatic toxicity): 1 M-factors are according to harmonised classification - Annex VI of Regulation (EC) No 1272/2008.		
		As described in REGULATION (EC) No 1272/2008 components classified as Acute 1 are considered for labelling only if the sum of the concentrations (in %) of these components multiplied by their corresponding M-factor is ≥ 25 %. In the case of 2-methyl-2H-isothiazol-3-one the concentration multiplied by the M-factor is below 25 % and therefore no labelling regarding 'Toxic to aquatic life or the environment' is needed.		
		Specific concentration limit. Skin sens. 1A; H317 >=0.0015%		



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4. First aid measures

4.1 Description of first aid measures

General advice: Move out of dangerous area. Show this safety data sheet to the doctor in attendance.

- After inhalation: Immediately remove the casualty from exposure and move to fresh air. If breathing stops, immediately apply mechanical ventilation and apply an oxygen mask if available. Arrange medical treatment.
- After skin contact: Wash off with plenty of water. Remove contaminated clothing. If necessary, arrange medical treatment.

After eye contact: Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.

After ingestion: Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

If first aid measures are adhered to: No acute or delayed effects. Otherwise: Irritation of skin, eyes.

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

Other than described in subsection 4.1: At the discretion of medical staff, depending on the casualty's condition.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: High volume water jet.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: No information available.

Hazardous combustion products: In case of fire hazardous decomposition products may be produced such as: Gaseous hydrogen chloride (HCI). Sodium oxides.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus for firefighting if necessary. Further information: Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

6. Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures

Do not inhale aerosols. Immediately change contaminated clothing.

6.2 Environmental precautions

Contain spillage. Prevent the mixtures from entering sewer systems.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section 13, Disposal considerations.



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7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling: Do not breathe vapours/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating, and drinking should be prohibited in the application area. Dispose of rinse water in accordance with local and national regulations. Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Advice on protection against fire and explosion: Normal measures for preventive fire protection.

Hygiene measures: Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards. Further information on storage conditions: See label, package insert or internal guidelines. Storage class (TRGS 510): 12, Non-combustible liquids. Further information on storage stability: No decomposition if stored and applied as directed.

7.3 Specific end use(s)

The product is intended only for professional use and only for the uses described in subsection 1.2.

8. Exposure controls/personal protection

8.1 Control parameters

Wear laboratory coat and protective gloves.

8.2 Exposure controls

Engineering measures: No data available

Personal protective equipment:

Tight fitting safety goggles Use eye protection according to EN 166.

Hand protection

In case of contact through splashing: Material: Nitrile rubber Break through time: > 30 min Glove thickness: > 0,11 mm In case of full contact: Material: butyl-rubber Break through time: > 480 min Glove thickness: > 0,4 mm

Remarks

The selected protective gloves must satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection

Impervious clothing.

Choose body protection according to the amount and concentration of the dangerous substance at the workplace.



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Physical and chemical properties 9.

9.1 Information on basic physical and chemical properties

Where nothing else is stated, data apply to all components.

Parameter	Value	Method/Reference	Comments
a) Appearance	Clear to yellow or red solutions	Visual check	
b) Odor	Odorless	NA	
c) Odor threshold	NA	NA	No data available on the components. No further investigated due to minimal relevance for these non-hazardous mixtures.
d) pH	Neutral, except Stop Solution: pH ~ 0.6	Glass electrode @ 25 °C	
e) Melting point/Freezing point	Data not available	NA	As c)
f) Initial boiling point and boiling range	Data not available	NA	As c)
g) Flash point	Data not available	NA	As c)
h) Evaporation rate	Data not available	NA	As c)
i) Flammability (solid, gas)	Data not available	NA	As c). Presumably not flammable.
j) Upper/lower flammability or explosive limits	Data not available	NA	As c) and i). Presumably not explosive.
k) Vapor pressure	Data not available	NA	As c)
I) Vapor density	Data not available	NA	As c)
m) Relative density	Data not available	NA	As c)
n) Solubility(ies)	Soluble in water	NA	As c)
o) Partition coefficient	Data not available	NA	As c)
p) Auto-ignition temperature	Data not available	NA	As c)
 q) Decomposition temperature 	Data not available	NA	As c)
r) Viscosity	Data not available	NA	As c)
s)Explosive propertiest)Oxidizing properties	Data not available Data not available	NA NA	As c). Presumably not explosive. As c)

9.2 Other information

Please note that Stop Solution contains sulfuric acid (H₂SO₄) and has a corrosive effect.

10. Stability and reactivity

10.1 Reactivity

Not reactive.

10.2 Chemical stability

Stable, no hazardous reaction when handled and stored according to provisions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products None known.



Safety Data Sheet (SDS) According to Regulation 2020/878 concerning REACH.

11. Toxicological information					
11.1 Information on haz	zards classes as defined in Regulation (EC) No 1272/2008				
Acute toxicity					
Not classified based on a	available information.				
Components:					
2-methyl-2H-isothiazol-	-3-one				
Acute oral toxicity:	LD50 (Rat, male and female): 120 mg/kg.				
	GLP: yes				
Acute inhalation toxicity:	LC50 (Rat, male and female): 0,11 mg/l				
	Exposure time: 4 h				
	Test atmosphere: dust/mist				
	Method: OECD Test Guideline 403				
	GLP: yes				
	Assessment: Corrosive to the respiratory tract.				
Acute dermal toxicity:	LD50 (Rat, male and female): 242 mg/kg				
	Method: OECD Test Guideline 402				
	GLP: yes				
Skin corrosion/irritation Not classified based on a					
Components:					
2-methyl-2H-isothiazol-	-3-one				
Species: Rabbit					
Exposure time: 4 h					
Method: OECD Test Gui	deline 404				
Result: Causes burns.					
GLP: yes					
Serious eye damage/ey	ve irritation				
Not classified based on a	available information.				
Components:					
2-methyl-2H-isothiazol-	-3-one				
Result: Risk of serious d					
Deenington, on chin com					
Respiratory or skin ser	ISITIZATION				
Skin sensitization	in reaction				
May cause an allergic sk					
Respiratory sensitization	on				
Not classified based on available information.					



Components:

2-methyl-2H-isothiazol-3-one

Test Type: Buehler Test Species: Guinea pig Assessment: May cause sensitization by skin contact. Method: OECD Test Guideline 406 Result: The product is a skin sensitizer, sub-category 1A. GLP: yes

Assessment: Fatal if inhaled.

Germ cell mutagenicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one

Genotoxicity in vitro: Test Type: Microbial mutagenesis assay (Ames test) Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative GLP: yes Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 473 Result: inconclusive GLP: yes

Genotoxicity in vivo:

Test Type: unscheduled DNA synthesis assay Species: Rat (male and female) Cell type: Liver cells Application Route: Oral Method: OECD Test Guideline 486 Result: negative GLP: yes

Carcinogenicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one Species: Rat, male and female Application Route: Oral



Exposure time: 2 Years

Frequency of Treatment: daily Method: OECD Test Guideline 453

Result: negative

GLP: yes

Remarks: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.

Reproductive toxicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one Effects on fertility: Test Type: Two-generation study Species: Rat, male and female Application Route: Oral Dose: 0, 50, 200, 1000 parts per million Duration of Single Treatment: 70 d Fertility: NOAEL: 69 mg/kg body weight Method: OECD Test Guideline 416 GLP: yes

Effects on fetal development: Species: Rat, females Application Route: Oral Duration of Single Treatment: 6 - 19 d Developmental Toxicity: NOAEL: 40 mg/kg body weight Method: OECD Test Guideline 414 GLP: yes

STOT - single exposure Not classified based on available information. STOT - repeated exposure Not classified based on available information.

Repeated dose toxicity <u>Components:</u> 2-methyl-2H-isothiazol-3-one Species: Rat, male and female

NOAEL: 19 mg/kg

Application Route: Oral Exposure time: 3 Months Dose: 0, 75, 225, 1000 parts per million Method: OECD Test Guideline 408 GLP: yes



Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards N.A.

12. Ecological information

12.1 Toxicity Components: 2-methyl-2H-isothiazol-3-one

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 4,77 mg/l End point: mortality Exposure time: 96 h Test Type: flow-through test Analytical monitoring: yes Method: OECD Test Guideline 203 GLP: yes

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0,934 mg/l End point: mortality Exposure time: 48 h Test Type: flow-through test Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: yes

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (microalgae)): 0,138 mg/l Exposure time: 120 h Test Type: static test Method: OECD Test Guideline 201 GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,05 mg/l Exposure time: 120 h Test Type: static test Method: OECD Test Guideline 201

GLP: yes M-Factor (Acute aquatic toxicity): 10

Toxicity to microorganisms: EC50 (activated sludge): 41 mg/l Exposure time: 3 h



Test Type: static test Analytical monitoring: no Method: OECD Test Guideline 209 GLP: yes

Toxicity to fish (Chronic toxicity): NOEC: 4,93 mg/l Exposure time: 98 d Species: Oncorhynchus mykiss (rainbow trout) Test Type: flow-through test Analytical monitoring: yes Method: OECD Test Guideline 210 GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0,044 mg/l

Exposure time: 21 d Species: Daphnia magna (Water flea) Analytical monitoring: yes Method: OECD Test Guideline 211 GLP: yes M-Factor (Chronic aquatic toxicity): 1

Ecotoxicology Assessment

Acute aquatic toxicity: Very toxic to aquatic life. Chronic aquatic toxicity: Very toxic to aquatic life with long lasting effects. Toxicity Data on Soil: Not expected to adsorb on soil. Other organisms relevant to the environment: No data available

12.2 Persistence and degradability

Components: 2-methyl-2H-isothiazol-3-one

Biodegradability

Test Type: aerobic Inoculum: activated sludge Result: Not readily biodegradable. Biodegradation: 50% Exposure time: 29 d Method: OECD Test Guideline 301B GLP: yes Remarks: The 10-day time window criterion is not fulfilled.

12.3 Bioaccumulative potential



Components:

2-methyl-2H-isothiazol-3-one

Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish) Exposure time: 56 d Bioconcentration factor (BCF): 5,75 GLP: no

Partition coefficient: noctanol/water: log Pow: -0,486 (20°C) pH: 7 Method: OECD Test Guideline 107 GLP: yes

12.4 Mobility in soil: No data available

12.5 Results of PBT and vPvB assessment: No data available

12.6 Endocrine disrupting properties: No data available

12.7 Other adverse effect

<u>Components:</u> **2-methyl-2H-isothiazol-3-one** Additional ecological information: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life.

13. Disposal considerations

13.1 Waste treatment methods

Product:

Do not contaminate ponds, waterways, or ditches with chemical or used container.

Send to a licensed waste management company.

Can be disposed of as wastewater, when in compliance with local regulations.

Contaminated packaging:

Empty remaining contents.

Dispose of as unused product.

Empty containers should be taken to an approved waste handling site for recycling or disposal.

Do not re-use empty containers.

14. Transport information

No special transport regulations apply.

14.1 UN number or ID number: Not regulated as a dangerous good

14.2 UN proper shipping name: Not regulated as a dangerous good

14.3 Transport hazard class(es): Not regulated as a dangerous good



14.4 Packing group: Not regulated as a dangerous good

14.5 Environmental hazards: Not regulated as a dangerous good

- 14.6 Special precautions for user:
 - Remarks:

Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

14.7 Maritime transport in bulk according to IMO instruments: N.A.

15. Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Water contaminating class: WGK 2 obviously hazardous to water

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorization (Article 59): Not applicable

REACH - List of substances subject to authorization (Annex XIV): Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AIIC: Not in compliance with the inventory

DSL: This product contains the following components that are not on the Canadian DSL nor NDSL. Sodium polystyrene sulfonate. Animal serum /-plasma - different species NZIoC: On the inventory, or in compliance with the inventory ENCS: Not in compliance with the inventory ISHL: Not in compliance with the inventory

KECI: Not in compliance with the inventory PICCS: Not in compliance with the inventory IECSC: Not in compliance with the inventory TCSI: Not in compliance with the inventory TSCA: Product contains substance(s) not listed on TSCA inventory.

Volatile organic compounds: Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control). Not applicable.



Labelling (REGULATION (EC) No 1272/2008)

Hazard pictogram:



Signal word: Warning Hazard statements: H317 may cause an allergic reaction

PRECAUTIONARY STATEMENTS

Prevention

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

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label

2682-20-4 2-methyl-2H-isothiazol-3-one

15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

16. Other information

Full text of H-Statements

H301: Toxic if swallowed.
H311: Toxic in contact with skin.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H330: Fatal if inhaled.
H335: May cause respiratory irritation.
H400: Very toxic to aquatic life.

Full text of other abbreviations

Acute Tox.: Acute toxicity Aquatic Acute: Short-term (acute) aquatic hazard Aquatic Chronic: Long-term (chronic) aquatic hazard Eye Dam: Serious eye damage Skin Corr: Skin corrosion Skin Sens: Skin sensitization STOT SE: Specific target organ toxicity - single exposure



ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant: DIN -Standard of the German Institute for Standardization: DSL - Domestic Substances List (Canada): ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS -Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP -Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization. ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization. KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL -International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified. NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance. PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern: TCSI - Taiwan Chemical Substance Inventory: TRGS -Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative.

Revision history			
Version	Change	Date	
01	New document	21FEB2023	

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.