

BioVendor – Laboratorní medicína a.s. Karásek 1767/1, 621 00 Brno, Czech Republic +420 549 124 185 info@biovendor.com

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SAFETY INFORMATION

Product name: HUMAN RBP4 (HIGH SENSITIVITY) ELISA

Catalogue number: RAG021R

Characteristics: The Human RBP4 (High sensitivity) ELISA Kit is to be used for the in vitro

quantitative determination of human RBP4 in serum, plasma, urine and cell culture

supernatant.

Intended use: For professional use only. Users should have a thorough understanding of the IFU

prior to their use of this kit.

Manufacturer: BioVendor – Laboratorní medicína a.s.

Registered office: Karásek 1767/1, 621 00 Brno, Czech Republic

Company ID: 63471507

Kit Components	Contents hazardous substance
Plate coated with human RBP4 Antibody	
Wash Buffer 10X	ProClin 300 < 0.025%
ELISA Buffer 10X	ProClin 300 < 0.025%
Detection Antibody	
HRP Conjugate 100X (HRP Conjugated anti-rabbit IgG)	
Human RBP4 Standard (lyophilized)	
TMB Substrate Solution	
Stop Solution	Sulphuric Acid < 5%

Safety Data Sheets in accordance with the current (EC/EU) Regulations as amended are attached.

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ProClin 300 < 0.025 %

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: ProClin 300 < 0.025 %

Other names:

Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) in

a concentration of 0.0025 - < 0.0250 %

UFI: Not apply.

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

No use descriptors (LCS, SU, PC, PROC, ERC, AC, TF categories) of the substance or mixture

Application of the substance / the mixture: Preservative agent for laboratory chemicals.

Uses advised against: Any other than the above mentioned.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.

Karásek 1767/1 621 00 Brno Czech Republic

Identification number: 63471507

Tel: +420 549 124 185 E-mail: <u>info@biovendor.com</u> Website: <u>www.biovendor.com</u>

Further information obtainable from:

Ing. Karel Královec, Studio2K, Czech Republic

Phone: +420 777 145 808, Email: <u>bl@studio2k.cz</u>,

Website: www.bezpecnostni-listy.eu

1.4 Emergency telephone number

European Chemicals Agency. National helpdesks contact details

https://echa.europa.eu/support/helpdesks

Links to Poison Centers and Clinical Toxicologists all over the World:

https://www.eapcct.org/index.php?page=links

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is classified as dangerous in the terms of the Regulation (EC) No 1272/2008 (CLP).

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aguatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

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

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Hazard pictograms:



Signal word: Warning

Hazard-determining components of labelling:

Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)

Hazard statements:

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P261 Avoid breathing mist/vapours/spray. P273 Avoid release to the environment.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of water.

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

Additional information: Void.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms:



Signal word: Warning

Hazard-determining components of labelling:

Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)

Hazard statements:

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects

Precautionary statements:

P261 Avoid breathing mist/vapours/spray.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of water.

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

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as PBT according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

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vPvB:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as vPvB according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

Determination of endocrine-disrupting properties

The mixture does not contain substances that have been identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:		
CAS: 55965-84-9 EC: 611-341-5	Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3one (3:1)	0.0025 ≤
INDEX: 613-167-00-5	Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330	0.025 %
	Skin Corr. 1C, H314; Eye Dam. 1, H318	
	Aquatic Acute 1, H400 (M=100); Aquatic Chronic 1, H410	
	(M=100)	
	Skin Sens. 1A, H317	
	EUH071 Specific concentration limits: Skin Corr. 1C; H314: $C \ge 0.6 \%$ Skin Irrit. 2; H315: $0.06 \% \le C < 0.6 \%$ Eye Dam. 1; H318: $C \ge 0.6 \%$ Eye Irrit. 2; H319: $0.06 \% \le C < 0.6 \%$	
	Skin Sens. 1A; H317: C ≥ 0.0015 % Note B	

Notes:

Note B:

Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations.

In Part 3 entries with Note B have a general designation of the following type: 'nitric acid .. %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

SVHC:

The product does not contain substances classified as of the date of preparation of the safety data sheet as PBT or vPvB and stated in the Candidate list of substances producing very high concerns for Appendix XIV of Regulation (EC) No 1907/2006 (REACH).

Regulation (EC) No 648/2004 on detergents / Labelling for contents: Not apply.

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Additional information:

The substances named in this section are given with their actual, appropriate classification! For substances that are listed in appendix VI, table 3 of the Regulation (EC) No 1272/2008 (CLP Regulation) this means that all notes that may be given here for the named classification have been taken into account. For the wording of the listed hazard phrases refer to section 16.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General information:

In case of doubt, appearance of symptoms or upon any problems, seek medical help and present this safety data sheet or the product label.

Never pour anything into the mouth of an unconscious person!

Personal protection for the First Aider.

Immediately remove any clothing soiled by the product.

After inhalation:

Remove person from danger area.

Take care of fresh air supply and seek medical assistance upon subsequent or lasting problems.

After skin contact:

Wash the affected skin with plenty of water. Upon skin irritation or other problems, consult further procedure with an expert physician.

After eye contact:

Open the eye lids, possibly remove contact lenses, and rinse the affected eyes thoroughly with clean flowing water. Upon skin irritation or other problems, consult further procedure with an expert physician.

After swallowing:

Thoroughly rinse the mouth with water and do not cause vomiting. Put the affected person in warm and calm conditions. Seek medical assistance immediately.

Information for doctor: Symptomatic treatment.

4.2 Most important symptoms and effects, both acute and delayed

Possible toxicological effects resulting from the classification are stated in Section 11. No further relevant information is available.

4.3 Indication of any immediate medical attention and special treatment needed

In case of ingestion seek medical help immediately.

For special medical advice, contact the Toxicology Information Centre.

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents:

No extinguishing substances are determined, the mixture is not flammable. Use fire extinguishing methods suitable to surrounding conditions.

For safety reasons unsuitable extinguishing agents: No unsuitable extinguishing materials are known.

5.2 Special hazards arising from the substance or mixture

No special dangers are determined.

Hazardous combustion products: Dangerous decomposition is not anticipated.

5.3 Advice for firefighters

Protective equipment:

No special measures required.

According to size of fire.

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Corresponding protective insulation breathing apparatus and overpressure counter-chemical protective clothing.

5.4 Further information

No relevant information is available.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Respect the instructions set forth in Sections 7 and 8 of the safety data sheet.

For non-emergency personnel:

Ensure adequate ventilation.

Use personal protective equipment.

Avoid contact with eyes and skin.

Prevent the possibility of slipping on the spilled product.

Prevent entry of unauthorised persons.

For emergency responders: See section 8 for suitable protective equipment and material specification.

6.2 Environmental precautions

The product is classified as dangerous for the environment.

Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust) and place into suitable and marked vessels.

Possibly wipe the leaked product with a paper towel and place it into a waste vessel.

Thoroughly wash the affected spot and the tools used with a suitable detergent, it is possible to use a larger quantity of water.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

In addition to the information provided in this section, important information is also provided in Sections 6 and 8.

Information about fire - and explosion protection:

No special measures required.

Respect general regulations on fire prevention.

Handling:

Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet.

Ensure good ventilation.

Prevent formation of aerosols.

Use personal protective equipment.

Avoid contact with eyes and skin.

Use working methods according to operating instructions.

Observe directions on label and instructions for use.

General hygiene measures for the handing of chemicals are applicable.

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Before a pause and after ending the work, wash the hands and take off the polluted working clothes. Keep these clothes separately.

Remove contaminated clothing and protective equipment before entering areas in which food is consumed.

Do not eat, drink, smoke, or snuff during use.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Secure impermeable floors against the liquids.

Store only in unopened original receptacles.

Information about storage in one common storage facility: Store away from foodstuffs.

Further information about storage conditions:

Store in a well ventilated place.

Store in a dry and cool place.

Keep containers tightly sealed.

Protect from exposure to the light.

Protect from frost.

Protect containers from physical damage.

Store under lock and key and with access restricted to technical experts or their assistants only.

Keep out of reach of children.

Recommended storage temperature: +2 °C to +8 °C.

7.3 Specific end use(s)

The product is intended only for professional use.

Specific use is stated in the manual for use on the product packaging label or in the product documentation.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

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

DNELs:			
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)			
Oral	DNEL - Long term exposure, systemic effects	0.09 mg/kg/d (consumers)	
	DNEL - Short term exposure, systemic effects	0.11 mg/kg/d (consumers)	
Inhalative	DNEL - Long term exposure, local effects	0.02 mg/m3 (consumers)	
		0.02 mg/m3 (workers)	
	DNEL - Short term exposure, systemic effects	0.04 mg/m3 (consumers)	
		0.04 mg/m3 (workers)	

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PNECs:		
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)		
PNEC - Freshwater	0.00339 mg/l	
PNEC - Marine water	0.00339 mg/l	
PNEC - Sewage treatment plant	0.23 mg/l	
PNEC - Sediment, freshwater	0.027 mg/kg	
PNEC - Sediment, marine water	0.027 mg/kg	
PNEC - Soil	0.01 mg/kg	
PNEC - Water (sporadic release)	0.00339 mg/l	

Ingredients with biological limit values:

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

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Ensure good ventilation. This can be achieved by local suction or general air extraction. If this is insufficient to maintain the concentration under WEL or IOEL values, suitable breathing protection should be worm. Applies only if maximum permissible exposure values are listed here.

8.2.2 Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Do not eat, drink, smoke or sniff while working.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

a) Eye/face protection:



Not required during regular use.

Alternatively, use closed safety glasses (EN 166).

b) Skin protection



Body protection

As needed, use the working protective clothes with long sleeves, possibly overalls, and protective working footwear.



Hand protection

Protective gloves (EN ISO 374-1).

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

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Preventive skin protection by use of skin-protecting agents is recommended.

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Material of gloves:

Nitrile rubber gloves (EN ISO 374-1).

Recommended thickness of the material: ≥ 0.11 mm.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. Glove material selection was performed based on the glove producers' data and information on substances contained in the product.

Penetration time of glove material:

≥ 480 minutes (EN 16523-1).

No tests have been performed, glove resistance must be tested before use. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

c) Respiratory protection:



Unnecessary during regular use.

In case of forming of vapours or aerosol, use a suitable breathing mask with a filter (EN 14387+A1).

Observe wearing time limitations for respiratory protection equipment.

Recommended filter device for short term use: Filter ABEK (EN 14387+A1).

d) Thermal hazards: Not applicable.

8.2.3 Environmental exposure controls:

Adhere to usual measures for environmental protection, see Section 6.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

General Information

Physical state: Fluid.

Colour:
Odour:
Not determined.
Not applicable.

Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Ignition temperature: Not applicable.
Decomposition temperature: Not determined.
pH: Not determined.

Viscosity

Kinematic viscosity: Not determined. Dynamic viscosity: Not determined.

Solubility

water: Not determined. Partition coefficient n-octanol/water (log value): Not determined. Vapour pressure: Not determined.

Density and/or relative density

Density:
Relative density:
Not determined.
Vapour density:
Not determined.
Not determined.
Relative gas density:
Not determined.
Not determined.

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9.2 Other information

Important information on protection of health and environment, and on safety.

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

Solvent content VOC (2010/75/EC): Not apply. Oxidising properties: Not determined. Evaporation rate: Not determined. Relative evaporation rate: Not determined.

Information with regard to physical hazard classes

Explosives: Void. Flammable gases: Void. Aerosols: Void. Oxidising gases: Void. Gases under pressure: Void. Flammable liquids: Void. Flammable solids: Void. Self-reactive substances and mixtures: Void. Pyrophoric liquids: Void. Pyrophoric solids: Void. Self-heating substances and mixtures: Void. Substances and mixtures, which emit flammable

gases in contact with water: Void. Oxidising liquids: Void. Oxidising solids: Void. Organic peroxides: Void. Corrosive to metals: Void Desensitised explosives: Void.

Additional information: No relevant information available.

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

10.2 Chemical stability

Upon adhering to the determined regulations of storage and uset he product is stable (see

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid.

Prevent contact with incompatible materials.

Protect against high temperatures.

Protect against frost.

10.5 Incompatible materials

Strong oxidizing and reducing agents

Amines.

Mercaptans.

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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SECTION 11 TOXICOLOGICAL INFORMATION

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

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

Relevant toxicological values for classification:		
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)		
Oral	LD50	53 mg/kg (rat)
Dermal	LD50	87 mg/kg (rabbit)
Inhalative	LC50/4 h	0.33 mg/l (rat)

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

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

Respiratory or skin sensitisation: May cause an allergic skin reaction.

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

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

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

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

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

Additional toxicological information: No relevant information is available.

Acute effects: No acute effects are known.

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

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction): No CMR effects are known.

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

Other information: No further information is available.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:

Hazardous to the aquatic environment - Aquatic Chronic 3.

55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)		
LC50/96 h	0.19 mg/l (fish) Oncorhynchus mykiss	
EC50/48 h	0.16 mg/l (daphnia) Daphnia magna	
EC50/72 h	> 0.037 mg/l (algae) Pseudokerchneriella subcapitata	
EC50/16 h	5.7 mg/l (bacteria) Pseudomonas putida	

12.2 Persistence and degradability

Ingredients are not expected to be resistant to biodegradation.

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55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-
isothiazol-3- one (3:1)

Biodegradability < 50 %/10 d

in water the substance is not readily biodegradable

Behaviour in waste water treatment plants: No relevant information is available.

12.3 Bioaccumulative potential

55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	
log Pow	0.401 measured value, bioaccumulation is not expected

Bioconcentration factor (BCF):

55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)		
BCF	3.6 calculated value	

12.4 Mobility in soil

55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	
log Koc	28 estimated value

12.5 Results of PBT and vPvB assessment

The product does not contain substances classified as PBT or vPvB and included in the list of substances subject to authorization (Annex XIV of EP and R Regulation No 1907/2006, as amended).

PBT: No relevant information is available. **vPvB:** No relevant information is available.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Remark: Harmful to fish.

Additional ecological information

AOX-indication: No relevant information is available.

General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Harmful to aquatic organisms.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation:

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

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Remove product residues according to the corresponding local directives in the adequate equipment as hazardous waste. E.g. put away at suitable waste dumps or remove in suitable waste incineration plants.

Waste disposal key:

The catalogue numbers with the asterisk (*) mark hazardous waste (N), numbers without the asterisk mark other waste (O).

The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances. (2001/118/EC, 2001/119/EC, 2001/573/EC, 2014/955/EU).

European waste catalogue and hazardous properties of waste:		
18 01 06*	chemicals consisting of or containing hazardous substances	
15 01 10*	packaging containing residues of or contaminated by hazardous substances	
15 01 02	plastic packaging	

Uncleaned packaging

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings may be reused.

Non contaminated packagings may be recycled.

Dispose of packaging that cannot be cleaned in the same manner as the mixture.

Empty container completely. Dispose of hazardous waste pursuant to corresponding local directives in adequate equipment. Put other waste away according to the material type into collection vessels for sorted waste.

Hand over possible empty packaging to an authorised organisation, which is entitled to their disposal.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

Regulations:

Commission Decision No 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council. Commission Regulation (EU) No 1357/2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.

SECTION 14 TRANSPORT INFORMATION

14.1 UN number or ID number

ADR, ADN IMDG, IATA: Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA Class: Void

14.4 Packaging group

ADR, IMDG, IATA: Void

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user

Unless specified otherwise, general measures for safe transport must be followed

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14.7 Maritime transport in bulk according to IMO instruments

Not applicable

Transport/Additional information: Non-dangerous material to Transport Regulations

UN "Model Regulation": Void

SECTION 15 INFORMATION

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

Directive 2004/42/EC of the European Parliament and the Council: Does not apply.

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

REGULATION (EC) No 1907/2006 ANNEX XVII: Conditions of restriction for the group No 3. DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II: None of the ingredients is listed. REGULATION (EU) 2019/1148:

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3)): None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS: None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors: None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors: None of the ingredients is listed.

Legal regulations of the European Community:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, as amended.

COMMISSION REGULATION (EU) amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures: 2016/918 (8. ATP from 1.2.2018), 2016/1179 (9. ATP from 1.3.2018), 2017/776 (10. ATP from 1.12.2018), 2018/669 (11. ATP from 1.12.2019), 2019/521 (12. ATP from 17.10.2020), 2018/1480 (13. ATP from 1.5.2020). COMMISSION DELEGATED REGULATION (EU) amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures:

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

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ProClin 300 < 0.025 %

SECTION 16 OTHER INFORMATION

Warning:

The safety data sheet contains data needed for securing safety and health protection during work and environ-mental protection. The stated data correspond to the current state of knowledge and experience and is in accord-ance with valid legal regulations. It cannot be deemed as a guarantee of the properties, suitability, and usefulness of the product for specific application and therefore no contractual legal relationships are hereby created.

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Relevant phrases:

H301 Toxic if swallowed.

H310 Fatal 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.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH071 Corrosive to the respiratory tract.

Training hints:

Pursuant to article No 35 of the European Parliament and Council Regulation (ES) No 1907/2006, the employer must allow employees or their representatives access to information from the safety data sheet of the substance or preparation, which the employees use or to the effects of which they may be exposed during their work.

Physical entities performed individual activities within the scope of handling of this hazardous product are trained and regularly, at least once a year, retrained.

Product information sources: safety data sheet, product or technical information, safety instructions, and other ex-pert documents for the product, issued by the supplier.

Recommended restriction of use:

The product is designed only for professional purposes. It must not be used in households. The product can only be handled by a person older than 18 years, who is sufficiently informed about the work procedures, hazardous properties of the product, and also about the necessary safety measures.

The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to ad-here to the product usage conditions and to respect the safety instructions for health and environmental protection.

Further information: This product must be stored, sold, and used in accordance with valid hygienic regulations.

Classification according to Regulation (EC) No 1272/2008:		
Skin sensitisation	Calculation	
Hazardous to the aquatic environment - long-term (chronic) aquatic hazard	method	

First issue of SDS: 30.09.2022 Internal code formula: 1670.003 Documents used to prepare SDS:

The original documents provided by the supplier or manufacturer related to the product (mixture), eventually to individual substances contained.

Abbreviations and acronyms:

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

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MATERIAL SAFETY DATA SHEET ProClin 300 < 0.025 %

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

VOC: Volatile Organic Compounds (USA, EU) DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2

Skin Corr. 1C: Skin corrosion/irritation - Category 1C

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1A: Skin sensitisation – Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Sources:

The safety data sheet was prepared in accordance with the European Parliament and Council Regulation (EC) No 1272/2008 (CLP) and according to the requirements of the European Parliament and Council Regulation (EC) No 1907/2006 about the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency - head IV, article 31, appendix II (instructions for safety data sheet compiling), as amended by the Commission Regulation (EU) No 2020/878 of 18 June 2020.

The missing ecotoxicology and toxicology data was obtained from the ESIS (European chemical Substances Information System), specifically from the IUCLID (International Uniform Chemical Information Database). As needed, data from further available chemical databases was used.

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Sulphuric Acid < 5 %

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: Sulphuric Acid < 5 % **Other name:** Sulfuric Acid < 5 %

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

Stop solution for the ELISA kit.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.

Karásek 1767/1 621 00 Brno Czech Republic

Identification number: 63471507

Tel: +420 549 124 185 E-mail: <u>info@biovendor.com</u> Website: <u>www.biovendor.com</u>

1.4 Emergency telephone number

European Chemicals Agency. National helpdesks contact details

https://echa.europa.eu/support/helpdesks

Links to Poison Centers and Clinical Toxicologists all over the World:

https://www.eapcct.org/index.php?page=links

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation 1272/2008/EC:

Corrosive to metals, Met. Corr. 1, H290

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200). (USA)

2.2 Label elements

Hazard pictogram:



GHS05

Signal word: Warning

Hazard statement:

H290 May be corrosive to metals.

Precautionary statement:

not assigned

2.2.1 Labelling of packages where the contents does not exceed 125 ml:

Hazard pictogram:

none

Signal word:

none

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Sulphuric Acid < 5 %

Hazard statement:

none

Precautionary statement:

none

Other hazards 2.3

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1 % or higher.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 **Mixtures**

Ingredient Conc. in w/w % EINECS CAS-Nr. Index-Nr. Sulphuric acid. 98 % < 5 231-639-5 7664-93-9 016-020-00-8 **REACH RN:** 01-2119458838-20-xxxx

Classification according to regulation 1272/2008/EC:

Met. Corr. 1. H290 Skin Corr. 1A, H314 Eye Dam. 1, H318

Specific concentration limits: Skin Corr. 1A, H314: C≥15 %; Skin Irrit. 2, H315: 5 %≤C<15 %; Eye

Irrit. 2, H319: 5 %≤C<15 %.

For full text of and H-phrases see section 16.

SECTION 4 FIRST AID MEASURES

Description of first aid measures 4.1

General information:

If feeling unwell or unsure, inform a doctor and show information from this Safety Data Sheet. If unconscious, place the affected person in the recovery position on their side with their head slightly backwards and take care there is no obstruction in their respiratory tract, NEVER induce vomiting. If the affected person is vomiting, ensure that they do not choke on their own vomit.

If inhaled: Immediately stop the exposure, take the affected person to fresh air. Keep the affected person warm. Get medical attention if irritation, shortness of breath or other symptoms persists.

In case of skin contact: Take off contaminated clothing. Wash the affected area with plenty of lukewarm water, if possible. If skin is not irritated, soap, soap solution or shampoo can be used. Get medical attention if irritation persists.

In case of contact with eyes: Rinse the eyes immediately with plenty of running water keeping eyelids open; if the affected person wears contact lenses, remove them immediately. Continue rinsing for minimum 10 minutes. Get medical attention.

If ingested: DO NOT INDUCE VOMITING - even the act of inducing vomiting may cause complications. Rinse mouth, if possible, administer a small dose of activated carbon (1-2 crushed tablets); do not attempt neutralization. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation: Possible respiratory tract irritation, cough, headache.

Skin contact: Painful reddening, irritation.

Eye contact: May cause irritation.

Ingestion: May cause irritation, sickness.

Indication of any immediate medical attention and special treatment needed 4.3

Immediate medical attention is not necessary.

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Sulphuric Acid < 5 %

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Alcohol resistant foam, carbon dioxide, powder, dispersed water, water spray.

Unsuitable extinguishing media: none known.

5.2 Special hazards arising from the substance or mixture

In case of fire sodium oxides can be released.

5.3 Advice for firefighters

Keep the contaminated fire-extinguishing media away from drains, surface and ground water. If necessary, wear a suitable self-contained breathing apparatus and full protective clothing.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Ensure sufficient ventilation. Wear proper protective equipment, refer to Section 8.

6.2 Environmental precautions

Avoid soil contamination and keep away from surface and ground water. Avoid spills and keep away from drains.

6.3 Methods and material for containment and cleaning up

Cover spills with suitable (non-flammable) absorbent (sand, diatomaceous earth, soil, and other suitable absorbent material); collect in a tightly closed container and dispose of in compliance with Section 13. Dispose of the contained material in accordance with local regulations. After containment, wash the affected area with plenty of water or other suitable detergent.

6.4 Reference to other sections

See section 7 for handling, section 8 for personal protective equipment, section 13 for disposal.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Do not inhale gases and vapours. Avoid contact with the skin and the eyes. Wear suitable personal protective equipment according to Section 8. Comply with local and national regulations on occupational health and safety. Avoid long-term and repeated exposure.

7.2 Conditions for safe storage, including any incompatibilities

Keep in tightly closed containers and in cool, dry and well-ventilated designated places. Open packaging must be carefully closed and kept in a vertical position to avoid release or spill. Keep away from alkaline materials.

7.3 Specific end use(s)

See Section 1.2., no other uses are identified.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Czech Republic (Government Decree no. 361/2007 Sb. as amended): Sulphuric acid, SO₃: long term 1 mg/m³, short term 2 mg/m³, note I (causes irritation of mucous membranes (eyes, respiratory tract) and skin irritation).

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Sulphuric Acid < 5 %

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Use in a well-ventilated area.

8.2.2 Individual protection measures, such as personal protective equipment

Take usual occupational health and safety measures. If it is impossible to meet exposition limits, suitable respiratory protective equipment must be used. When using, do not eat, drink and smoke. Wash hands carefully with water and soap after work and before breaks.

a) Eye/face protection:



Use protective glasses (according to EN 166).

b) Skin protection:



Hand protection:

Use suitable protective gloves resistant to the product. Follow the recommendations of the gloves manufacturer when selecting the appropriate thickness, material and permeability. In the event of long-term or repeated dermal exposure, apply suitable hand cream to the parts of the skin in direct contact with the mixture. Follow other recommendations of the manufacturer.



Body protection:

Protective cotton clothing. Carefully wash the skin exposed to the product.

c) Respiratory protection:



If necessary, wear a face respirator (according to EN 14387).

d) Thermal hazards: No information available.

8.2.3 Environmental exposure controls

Refer to Sections 6 and 12.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state: Liquid
Colour: Colourless
Odour: Odourless
Odour threshold: Not determined

pH: 0.8

Melting point/freezing point (°C): No data available

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Sulphuric Acid < 5 %

Initial boiling point and boiling range (°C):

Flash point (°C):

Evaporation rate:

Flammability:

No data available

No data available

No data available

No data available

Upper/lower flammability or

explosive limits:

Vapour pressure:

No data available

No data available

Vapour density:

Relative density:

Solubility:

No data available
Soluble in water

Partition coefficient n-octanol/water: Auto-ignition temperature (°C): Decomposition temperature:

Viscosity:

Explosive properties:

Oxidizing properties:

No data available

No data available

No data available

9.2 Other information

None known.

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

No hazardous reactions occur under common conditions of use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Reacts with strong bases.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Not known under recommended conditions of use.

10.6 Hazardous decomposition products

They are not produced under normal use. In the event of fire: sulphur oxides.

SECTION 11 TOXICOLOGICAL INFORMATION

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

Acute toxicity: The classification criteria are not met.

Sulphuric acid:

LD50, oral, rat: 3140 mg/kg LD50, inhalation, rat: 510 mg/m³/2 h

Skin corrosion/ irritation: The classification criteria are not met. May cause mild

irritation.

Serious eye damage/ irritation: The classification criteria are not met. May cause mild

irritation.

Respiratory or skin sensitisation:
Germ cell mutagenicity:
Carcinogenicity:
The classification criteria are not met.

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Sulphuric Acid < 5 %

Aspiration hazard: The classification criteria are not met.

Reproduction toxicity: No data available.

11.2 Information on other hazards

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1 % or higher.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

No data available on the product itself.

Sulphuric acid:

LC50, fish, Gambusia affinis, 96 h: 42 mg/l LC50, crustaceans, Pandalus montagui, 48 h: 42,5 mg/l

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Does not meet the criteria for PBT and vPvB.

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1 % or higher.

12.7 Other adverse effects

No data available.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with applicable national regulations, to regulate packaging and to amend some statutes (the Packaging Act), as amended and in accordance with implemented regulations on waste disposal.

Appropriate methods of waste treatment of both the substance or the mixture and any contaminated packaging:

The indicated waste, including the waste identification sheet, shall be handed over to a company authorized to treat and dispose of wastes according to the Waste Act and that the company producing waste has entered into a contract with.

Both completely empty and not completely empty packaging shall be placed in designated containers for waste collection and the indicated waste shall be handed over for disposal to a person authorized to dispose of the waste.

Waste type code 060101

Waste type sulphuric acid and sulphurous acid *

Waste subgroup waste from production, processing, distribution and use

(VZDP) of acids

Waste group WASTE CREATED BY ANORGANIC CHEMICAL

PROCESSES

Waste type code for packaging 150110

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Sulphuric Acid < 5 %

Waste type packaging containing residues of dangerous substances or

packaging contaminated with these substances*

Waste subgroup Packaging (including separately collected household

packaging material)

Waste group WASTE PACKAGING; ABSORPTION AGENTS;

CLEANING CLOTHS; FILTRATION MATERIALS AND PROTECTIVE CLOTHING NOT SPECIFIED IN ANY

OTHER MANNER

(*) - hazardous waste according to Directive No. 91/689/EEC on hazardous waste

SECTION 14 TRANSPORT INFORMATION

14.1 UN number or ID number

3264.

14.2 UN proper shipping name

CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (sulphuric acid).

14.3 Transport hazard class

8.

14.4 Packing group

III.

14.5 Environmental hazards

No

14.6 Special precautions for user

No data available.

14.7 Maritime transport in bulk according to IMO instruments

No data available.

SECTION 15 REGULATORY INFORMATION

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

Act No. 350/2011 Coll., to regulate chemical substances and chemical mixtures and to amend some statutes, as amended. Implemented regulations to Act No. 350/2011 Coll., as amended The Waste Act as amended. Government Decree No. 361/2007 Coll., to regulate the conditions of occupational health and safety, as amended. Regulation of the European Parliament and the Council (EC) No. 1907/2006 (REACH). Regulation of the European Parliament and the Council (EC) No. 1272/2008 (CLP). Commission Regulation (EU) No. 878/2020.

U.S. Federal regulations:

TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): All components are listed or exempted.

Clean Water Act (CWA) 311: sulphuric acid.

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Warning:

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Sulphuric Acid < 5 %

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Relevant phrases:

H290	May be corrosive to metals.	
H314	Causes severe skin burns and e	ye damage.
H315	Causes skin irritation.	
H318	Causes serious eye damage.	
H319	Causes serious eye irritation.	
Hazardous Material Information System (U.S.A.)		
Health	-	1
Chronic	Health Hazard	
Flammability		0
Physical Hazards		0
Nationa	I Fire Protection Association (U	.S.A.)
Health	,	1
Flamma	bility	0
Instability/Reactivity		0
Special	•	

Training hints:

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Physical entities performed individual activities within the scope of handling of this hazardous product are trained and regularly, at least once a year, retrained.

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The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to ad-here to the product usage conditions and to respect the safety instructions for health and environmental protection.

Further information: This product must be stored, sold, and used in accordance with valid hygienic regulations.

Date of issue: 30.5.2022

Revision notes: Commission Regulation (EU) No. 830/2015 was replaced by Commission Regulation (EU) No. 878/2022. Change of classification of the mixture. Exception for labelling of packaging not exceeding 125 ml, addition of REACH RN of the component, change of section 11 structure, addition of transport information in section 14.

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