

SAFETY INFORMATION

Product name: PREGNENOLONE ELISA
Catalogue number: RCD022R
Characteristics: For the direct quantitative determination of Pregnenolone by enzyme immunoassay in human serum.
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
Rabbit Anti-Pregnenolone Antibody-Coated Microplate	
Pregnenolone-Horseradish Peroxidase (HRP) Conjugate Concentrate	
Pregnenolone Calibrators	
Controls	
Wash Buffer Concentrate	
Assay Buffer	
TMB Substrate	
Stopping Solution	Sulphuric Acid < 10%

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

Sulphuric Acid < 10 %

SECTION 1	IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING
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1.1 Product identifier**Trade name:** Sulphuric Acid < 10 %**Other name:** Sulfuric Acid < 10 %**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: info@biovendor.comWebsite: www.biovendor.com**1.4 Emergency telephone number**

European Chemicals Agency. National helpdesks contact details

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

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

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

SECTION 2	HAZARDS IDENTIFICATION
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2.1 Classification of the substance or mixture**Classification according to Regulation (EC) No 1272/2008**

Corrosive to Metals (Category 1), H290

Skin irritation (Category 2), H315

Eye irritation (Category 2), H319

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements**Hazard pictogram:**

GHS05

Signal word: Warning**Hazard statement(s):**

H290 May be corrosive to metals.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statement(s):

P234 Keep only in original packaging.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face protection.

Sulphuric Acid < 10 %

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

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P332 + P313 If skin irritation occurs: Get medical advice/attention

Supplemental Hazard Statements: none

Reduced Labelling (≤ 125 ml)

Hazard pictogram: none

Signal word: Warning

Hazard statement(s): none

Precautionary statement(s): none

Supplemental Hazard Statements: none

2.3 Other hazards

This substance/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 - < 10	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 %; Met. Corr. 1, H290: C≥0.3 %.

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

SECTION 4 FIRST AID MEASURES**4.1 Description of first aid measures****If inhaled**

After inhalation: fresh air.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

Sulphuric Acid < 10 %**SECTION 5 FIREFIGHTING MEASURES****5.1 Extinguishing media****Suitable extinguishing media**

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

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Sulphur oxides Not combustible.

Ambient fire may liberate hazardous vapours.

Fire may cause evolution of:

Sulphur oxides

5.3 Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

5.4 Further information

Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6 ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment, and emergency procedures**

Advice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. Advice for emergency responders: Protective equipment see section 8.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and material for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent and neutralising material. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7 HANDLING AND STORAGE**7.1 Precautions for safe handling****Advice on safe handling**

Observe label precautions.

Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities**Storage conditions**

No metal or light-weight-metal containers. Tightly closed.

Recommended storage temperature see product label.

Sulphuric Acid < 10 %
Storage class

Storage class (TRGS 510): 8B: Non-combustible, corrosive hazardous materials

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8	EXPOSURE CONTROLS / PERSONAL PROTECTION
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8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls
8.2.1 Personal protective equipment
a) Eyeface protection:


Safety glasses

b) Skin protection:


Body protection: acid-resistant protective clothing

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use.



Hand protection:

When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves. This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use.

c) Respiratory protection:


Recommended Filter type: Filter type P2

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

d) Thermal hazards: Not applicable.

8.2.2 Environmental exposure controls

Do not let product enter drains.

SECTION 9	PHYSICAL AND CHEMICAL PROPERTIES
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9.1 Information on basic physical and chemical properties

Physical state:

liquid

Color:

colorless

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Sulphuric Acid < 10 %

Odor:	odorless
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability (solid, gas):	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point:	Not applicable
Autoignition temperature:	No data available
Decomposition temperature:	No data available
pH:	ca.1 at 20 °C
Viscosity:	
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Water solubility:	soluble, (development of heat)
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	No data available
Density:	1,1 g/cm ³ at 20 °C
Relative density:	No data available
Relative vapor density:	No data available
Particle characteristics:	No data available
Explosive properties:	Not classified as explosive.
Oxidizing properties:	Oxidizing potential

9.2 Other information

No data available

SECTION 10 STABILITY AND REACTIVITY
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10.1 Reactivity

Oxidizing agents

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Violent reactions possible with:

Water

Alkali metals

alkali compounds

Ammonia

alkalines

Metals

Alkaline earth metals alkaline earth compounds

metal alloys

Acids

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

animal/vegetable tissues, metals - gives off hydrogen by reaction with metals.

10.6 Hazardous decomposition products

In the event of fire: see section 5

Sulphuric Acid < 10 %

SECTION 11	TOXICOLOGICAL INFORMATION
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11.1 Information on toxicological effects

Acute toxicity:	The classification criteria are not met.
Sulphuric acid:	
Oral:	No data available
Inhalation:	No data available
Dermal:	No data available
Skin corrosion/irritation:	No data available
Serious eye damage/eye irritation:	No data available
Respiratory or skin sensitization:	No data available
Germ cell mutagenicity:	No data available
Carcinogenicity:	No data available
Reproductive toxicity:	No data available
STOT - single exposure:	No data available
STOT - repeated exposure:	No data available
Aspiration hazard:	No data available

11.2 Additional Information
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.

After inhalation of vapours: irritative symptoms in the respiratory tract. After skin contact: severe irritations. After eye contact: corneal destruction. After swallowing: damage of the oral, oesophageal, and gastric mucous membranes. Perforation of the oesophagus frequently occurs. Circulatory collapse may occur after 1-2 hours.

Other dangerous properties cannot be excluded.

Handle in accordance with good industrial hygiene and safety practice.

Acute toxicity

Sulphuric acid:	
LD50 Oral - Rat - male and female:	2.140 mg/kg; Remarks: (ECHA)
Inhalation:	Corrosive to respiratory system.
Dermal:	No data available
Skin corrosion/irritation:	Skin – Rabbit Result: Extremely corrosive and destructive to tissue. Remarks: (IUCRID)
Serious eye damage/eye irritation:	Causes serious eye damage.
Respiratory or skin sensitization:	No data available
Germ cell mutagenicity:	Test Type: Ames test Test system: Salmonella typhimurium Result: negative Remarks: (HSDB)
Carcinogenicity:	No data available
Reproductive toxicity:	No data available
STOT - single exposure:	No data available
STOT - repeated exposure:	No data available
Aspiration hazard:	No data available

SECTION 12	ECOLOGICAL INFORMATION
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12.1 Toxicity

Mixture
No data available

Sulphuric Acid < 10 %
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

This substance/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.

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

Harmful effect due to pH shift.

Neutralisation possible in waste water treatment plants.

Discharge into the environment must be avoided.

Sulphuric acid:

Toxicity to daphnia and other aquatic invertebrates:

static test EC50 - Daphnia magna (Water flea) - > 100 mg/l - 48 h (OECD Test Guideline 202)

Toxicity to algae:

static test EC50 - Desmodesmus subspicatus (green algae) - > 100 mg/l – 72 h (OECD Test Guideline 201)

SECTION 13	DISPOSAL CONSIDERATIONS
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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

Waste type packaging containing residues of dangerous substances or packaging contaminated with these substances *

Waste subgroup Packaging (including separately collected household packaging material)

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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

ADR/RID: 2796

IMDG: 2796

IATA: 2796

14.2 UN proper shipping name

ADR/RID: SULPHURIC ACID

IMDG: SULPHURIC ACID

IATA: Sulphuric acid

14.3 Transport hazard class(es)

ADR/RID: 8

IMDG: 8

IATA: 8

14.4 Packaging group

ADR/RID: II

IMDG: II

IATA: II

14.5 Environmental hazards

ADR/RID: no

IMDG: Marine pollutant: no

IATA: no

14.6 Special precautions for user

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.

Authorisations and/or restrictions on use

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors: sulphuric acid

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16 OTHER INFORMATION
Full text of H-Statements referred to under sections 2 and 3.

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of

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In accordance with Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) and Commission Regulation (EU) No. 878/2020

Sulphuric Acid < 10 %

Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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 Organisation 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, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Classification of the mixture

Classification procedure:

Met. Corr.1, H290	Based on product data or assessment
Skin Irrit.2, H315	Calculation method
Eye Irrit.2, H319	Calculation method

Further information**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 adhere 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.

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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.