

Safety Information

17α-hydroxyprogesterone (17α-OHP) ELISA

Revision Date: 14.3.2017

The RCD021R 17 α -hydroxyprogesterone (17 α -OHP) ELISA is an enzyme immunoassay for the direct quantitative determination of 17 α -hydroxyprogesterone in human serum.

For professional use only. Users should have a thorough understanding of the Product Data Sheet prior to their use of this kit.

Kit Components:

- A) Rabbit Anti-17α-OHP Antibody Coated Microwell Plate-Break Apart Wells
- B) 17α-OHP-Horseradish Peroxidase (HRP) Conjugate
- C) 17α-OHP Calibrators
- D) Controls
- E) Wash Buffer Concentrate
- F) Assay Buffer
- G) TMB Substrate
- H) Stopping Solution

Stopping Solution containing sulphuric acid is a hazardous mixture according to CLP Regulation (EC) as amended.

Safety Data Sheet for Sulphuric Acid < 10% according to actual Regulations (EC/EU) is attached. The other components do not contain any hazardous mixture according to CLP Regulation (EC) as amended.



in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) and Commission Regulation (EU) No. 830/2015

Sulphuric Acid < 10%

Date of issue: 28.7.2015 Supersedes date: 17.6.2015

SECTION 1 IDENTIFICATION OF THE PREPARATION AND OF COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Sulphuric Acid < 10% Additional identification: Sulfuric Acid < 10%

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

Relevant identified uses: to be used as a component with ELISA kits according to the instructions

provided with the kit.

Uses advised against: not available

1.3 Company identification:

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.com

1.4 Emergency telephone number:

Toxicology information centre, Na Bojišti 1, 128 21 Prague, Czech Republic, Tel: +420 224 919 293 or +420 224 915 402 (non-stop service).

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification according to the regulation (EC) No. 1272/2008 (CLP) and its amendments

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

2.2 Label elements according to the regulation (EC) No. 1272/2008 (CLP) and its amendments

Danger symbol

Signal word Warning

Product Identifier Sulphuric Acid < 10% w/w
Danger H315 Causes skin irritation.

H319 Causes serious eye irritation.

Supplemental Hazard

Information

Prevention statements P264 Wash exposed skin thoroughly after handling.

P280 Wear protective gloves, protective clothing, eye protection, face

protection.



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Response statements P302+P350 IF ON SKIN: Gently wash with plenty of soap and water.

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

P305+P351+P338 If in eyes: Rinse cautiously with water for several

minutes.

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

Storage statements

Disposal statements P501 Dispose of contents/container to comply with local, state and

federal regulations.

2.1 Other hazards:

Results of PBT and vPvB evaluation:

PBT: Not applicable vPvB: Not applicable

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Name	(% w/w)	Classification	Specific concentration limits
Sulfuric acid%* CAS: 7664-93-9 EC: 231-639-5 Index number: 016-020-00-8	< 10%	Skin Corr. 1A, H314	Skin Corr. 1A; H314: C ≥ 15% Eye Irrit. 2; H319: 5% ≤ C < 15% Skin Irrit. 2; H315: 5% ≤ C < 15%

*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.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General information In general, in case of doubt or if symptoms persist, always call a doctor.

Never give anything by mouth to an unconscious person.

Following inhalation If person experiences nausea, headache or dizziness, person should

stop work immediately and move to fresh air until these symptoms disappear. If breathing is difficult, administer oxygen by a qualified person, keep the person warm and at rest. Call a physician. In the event that an individual inhales enough vapour to lose consciousness, person should be moved to fresh air at once and a physician should be called immediately. If breathing has stopped, artificial respiration should be given immediately. In all case, ensure adequate ventilation and provide

respiratory protection before the person returns to work.

Following skin contact IF ON SKIN (or hair): Remove contaminated clothing. Rinse skin with

water / with vegetable oil. Take a shower.

If irritation or rash occurs: Get medical advice.



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Following eye contact IF IN EYES: Rinse cautiously with vegetable oil for several minutes.

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

If eye irritation persists: Get medical advice/attention.

Following ingestion IF SWALLOWED: Rinse thoroughly mouth with water. Immediately call

a POISON CENTER/doctor.

Do NOT induce vomiting.

For emergency resp. No data available.

SECTION 5 FIRE-FIGHTING MEASURES

5.1 Extinguishing media

<u>Appropriated:</u> Use water spray or other suitable agent on fires adjacent to nonleaking tanks or intact containers of acid. If only a small amount of combustibles is present, smother fire with dry chemical.

Small fire: Dry powder or CO₂. Move containers from fire area, if it can be done without risk.

Large fire: Flood fire area with large quantities of water, while knocking down vapours with water fog. Cool containers with flooding quantities of water until well after fire is out. Do not get water inside containers. Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank.

Non-appropriated: Do not use solid water streams near ruptured tanks or spills of sulfuric acid.

5.2 Special hazards arising from the substance or mixture

Acid reacts violently with water and can spatter acid onto personnel.

Reacts with most metals, especially when diluted: Hydrogen gas release, which is extremely flammable and explosive. Risk of explosion if acid combines with water, organic materials or base solutions in enclosed spaces. Mixing acids of different strengths/concentrations can also pose an explosive risk in an enclosed space/container.

5.3 Advice for firefighters

Add chemical safety goggles if eye protection is not provided. Wear full protective clothing. Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear full protective clothing. Neutralize run-off with lime, soda ash, to prevent corrosion of metals and formation of hydrogen gas. Wear self-contained breathing apparatus if fumes or mists are present.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate all personnel from danger area.

Use required personal protective equipment.

Remove sources of ignition.

DO NOT smoke.

Stop flow if possible.

6.2 Environmental precautions

Avoid release to the environment.

Avoid contamination of drains, surface water and groundwater.



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6.3 Methods and material for containment and cleaning up

SMALL SPILL: Soak up with dry sand, clay or diatomaceous earth.

LARGE SPILL: Dike. Cautiously dilute and neutralize with lime or soda ash. Adequate ventilation is required during neutralization due to release of CO₂ gas. Transfer to waste water treatment system. Prevent liquid from entering sewers, waterways. Product not recovered or sent as waste for treatment should be reported to authorities.

6.4 Reference to other sections

Refer to sections: 7 safe handling, 8 for personal protective equipments, 13 for disposal.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

DO NOT get in eyes, on skin, or on clothing.

DO NOT ingest: Avoid breathing vapours or mist.

Wear approved respirators if ventilation is not adequate.

No eating, drinking and smoking when handling the product.

Wash hands thoroughly after handling.

NEVER add water to acid.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, well-ventilated area, away from incompatible substances. Protect from physical damage.

Keep out of sun and away from heat (more than 275°C).

If stored in metal containers, vapours can contain explosive hydrogen gas.

Do not smoke in storage area.

7.3 Specific end use(s)

No data available.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

Sulphuric acid:

Limit value (8h): 1 mg/m³

Limit value (Short term): 3 mg/m³

8.2 Exposure controls

Appropriate engineering controls:

Good general ventilation should be provided to keep vapour and mist concentrations below the exposure limits.

<u>Eye/face protection:</u> Wear safety glasses with non-perforated shields. Add a face shield (close-fitting) if pouring liquid. For leak, spills emergency or heavy handling, use chemical safety goggles or a full face shield. Do not wear contact lenses.



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Respiratory protection: Not required when using a closed ventilation system. If acid concentration is above 1 mg/m³, wear a gas mask with acid gas canister equipped with particulate filter. If the concentration is higher than 10 mg/m³, use an efficiency particulate respirator, or self-contained breathing apparatus with full face piece.

Other: Wear acid resistant gloves (preferably rubber), boots; long sleeve wool, acrylic, or polyester clothing under an acid proof suit. Trouser legs should be outside boots. An apron can be used in place of acid proof suit in laboratory environment, or in handling small volumes of sulphuric acid. In case of emergency, wear a complete acid suit with hood, boots, and gloves with respiratory protection.

Environmental exposure controls: Avoid release to the environment.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state Liquid

Viscous

Colour Colourless to slightly yellow

Odour Not available
Odor threshold Not available

pH <1
Melting / Freezing point -14°C
Boiling point 308°C

Flash point Not applicable

Evaporation rate <1

Flammability

Lower limit of flammability or explosive

Upper limit of flammability or explosive

Not available

Not applicable

Vapour pressure <0.001 mmHg @ 20°C

Vapour density 3.4 (air = 1)Relative density 1.84 Water solubility Miscible Solubility in other Solvents Not available Not available Log Kow Auto-inflammability temperature Not applicable Decomposition temperature Not available Viscosity Not available Explosive properties Not available Oxidizing properties Not available Refractive index Not available

9.2 Other information

No data available.



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SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

Reacts violently with water, organic substances and base solutions with evolution of heat.

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Under normal conditions of stock and use, hazardous reactions will not occur.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Vigorous reactions with: water, alkaline solutions, metals, carbides, chlorates, fulminates, nitrates, picrates, strong oxidizing, reducing or combustible organic materials. Hazardous gases are evolved on contact with chemicals such as cyanides, sulfides and carbides.

10.6 Hazardous decomposition products

Temperatures of ≥ 275°C yield sulphur trioxide gas, which is toxic, corrosive and an oxidizer

SECTION 11 TOXICOLOGICAL INFORMATION

Acute toxicity	Highly toxic. Erosion of teeth, lesions of the skin, bronchitis,
	mouth inflammation, conjunctivitis, gastritis.

LD50 (rat-oral) = 2140 mg/kg

LC50 (mouse-ihl) = 160 mg/m^3 (4hrs) LC50 (rat-ihl) = 255 mg/m^3 (4 hrs)

Inhalation Highly toxic by inhalation of fumes or acid mist. Causes

irritations or corrosive burns to the upper respiratory system, including nose, mouth, and throat. Lung irritation and pulmonary

edema can also occur.

Ingestion Can cause irritation and corrosive burns to mouth, throat, and

stomach. Can be fatal if swallowed. Risk of vomiting, diarrhea,

oesophagus and stomach perforation.

Skin corrosion Can cause severe burns and destruction of tissue. May cause

destruction of the dermis with impairment of the skin at site of

contact to regenerate.

Eye damage Extremely corrosive! Liquid contact causes irritation, corneal

burns, and conjunctivitis. Blindness may result, or severe or

permanent injury. Mist contact may irritate or burn.

Respiratory sensibilisation Not available.

Germ cell mutagenicity Not identified as a mutagen. Carcinogenicity Suspected in humans.

Toxic for reproduction Not identified as toxic for reproduction.

Unique specific toxicity

Repeated specific toxicity

Not available.

Not available.



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Aspiration hazard Not available.

Other information Practical experience: none.

General notes: The classification was made according to the calculation procedure of the preparation and harmonized

classification.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to aquatic life increases with lowering of pH.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Sulphate ion: Ubiquitous in the environment. Metabolized by micro-organisms and plants without bioaccumulation.

12.4 Mobility in soil

Easy soil seeping under rain action.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Due to the product's composition, particular attention must be taken for transportation and storage. Protect from rain because the run-off water will become acidic and may be harmful to flora and fauna.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Do not use the empty containers.

Waste disposal according to the Directives EC 75/442/EEC and 91/689/EEC in their latest versions by incineration or dispose of waste material.

13.2 Waste code numbers/Waste identification

No data available.

SECTION 14 TRANSPORT INFORMATION

ADR / ADN/ADNR / IMDG / ICAO

UN number Not applicable
UN proper shipping name Not applicable
Transport hazard class(es) Not applicable
Packing group Not applicable
Environmental hazards Not available



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Hazard label Not applicable
Classification code Not applicable
Special precautions for user Not available

Transport in bulk according to AnnexII of MARPOL73/78

and the IBC Code Not available
Other information Not 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. 830/2015.

15.2 Chemical safety assessment

No data available

SECTION 16 OTHER INFORMATION

16.1 Indication of changes (Additions, Deletions, Revisions)

Date of issue: 28.7.2015 Supersedes date: 17.6.2015

16.2 Key or legend to abbreviations and acronyms

ADN/ADNR: Regulations concerning the transport of dangerous substances in barges on

inland waterways.

ADR/RID: European Agreement concerns the International Carriage of Dangerous Goods

by Road/ Regulations concerning the international carriage of dangerous goods

by rail.

CAS No.: Chemical Abstract Service Number CLP: Classification, Labelling and Packaging

16.3 Key literature references and sources for data

No data available.

16.4 Procedure used to derive the classification according to regulation (EC) No. 1272/2008 (CLP)

Classification of the mixture is consistent with the method of valuation of regulation (EC) No. 1272/2008.



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16.5 List of relevant hazard statements and/or precautionary statements (Full text of any statements which are not written out in full under section 3).

Hazard statements (H):

H314 Causes severe skin burns and eye damage.

16.6 Advice on any training appropriate for workers to ensure protection of human health and the environment

No data available

Note:

The safety data sheet contains data necessary for ensuring occupational health and safety and protection of the environment. The given data correspond to the current state of knowledge and experience and comply with valid legal regulations. The data cannot be considered a guarantee that the specific use of the product will be appropriate.