

Safety Information

17-OH-Progesterone free in Saliva ELISA

Revision Date: 29.4.2019

The RTC010R 17-OH progesterone free in Saliva ELISA is an enzyme immunoassay for the quantitative in vitro diagnostic measurement of active free 17-hydroxyprogesterone in saliva. 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) Microtiterplate
- B) Standards (Standard 0-5)
- C) Quality Control HIGH and LOW
- D) Enzyme Conjugate
- E) Wash Solution
- F) Substrate Solution
- G) Stop Solution

The above components do not contain any hazardous mixture according to CLP Regulation (EC) as amended.

Safety Data Sheet for the Sulphuric Acid < 5% (present in Stop Solution) according to actual Regulations (EC/EU) is attached.

MATERIAL SAFETY DATA SHEET

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 < 5%

Date of issue: 30.7.2015

Supersedes date:

SECTION 1 IDENTIFICATION OF THE PREPARATION AND OF COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: Sulphuric Acid < 5%

Additional identification: 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: 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 of the substance or mixture

Classification according to Regulation 1272/2008/EC:

Not classified as dangerous.

2.2 Label elements

Not applicable.

EUH210 Safety data sheet available on request.

2.3 Other hazards

Concentration limits for classification as dangerous are not met.

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

Classification according to regulation 1272/2008/EC:

Skin Corr. 1A, H314

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 H-phrases see section 16.

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SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

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.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate medical attention is not necessary.

SECTION 5 FIRE-FIGHTING 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.

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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).

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: i) *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

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cream to the parts of the skin in direct contact with the mixture. Follow other recommendations of the manufacturer.

ii) Other: 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

Appearance (at 20°C):	Colourless liquid
Odour:	Odourless
Odour threshold:	Not determined
pH:	
Melting point/freezing point (°C):	No data available
Initial boiling point and boiling range (°C):	No data available
Flash point (°C):	No data available
Evaporation rate:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Vapour pressure:	No data available
Vapour density:	
Relative density:	No data available
Solubility(ies):	Soluble in water
Partition coefficient n-octanol/water:	
Auto-ignition temperature (°C):	
Decomposition temperature:	
Viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	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.

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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 toxicological effects

Acute toxicity:

No data available on the product itself.

Sulphuric acid:

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

Corrosion/ irritation: May cause mild irritation. Product is not classified as irritant.

Chronic toxicity

Sensitisation: No data available.
Narcotic effects: No data available.
Carcinogenicity: No data available.
Mutagenity: No data available.
Reproduction toxicity: No data available.

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 biodegradability

No data available.

12.3 Bioaccumulative potencial

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 Other adverse effects

No data available.

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SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Proceed in accordance with Act No. 185/2001 Coll., the Waste Act, as amended, Act No. 188/2004 Coll., to amend Act No. 185/2001 Coll.; Act No. 477/2001 Coll., 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)
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

Not regulated.

14.2 UN proper shipping name

Not regulated.

14.3 Transport hazard class(es)

Not regulated.

14.4 Packing group

Not regulated.

14.5 Environmental hazards

No data available.

14.6 Special precautions for user

No data available.

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14.7 Transport in bulk according to Annex II of Marpol73/78 and the IBC Code

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. 830/2015.

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16 OTHER INFORMATION

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Full text of H-phrases:

H314 Causes severe skin burns and eye damage.

Advice on training

Workers shall receive appropriate training to acquaint them with the recommended use, mandatory protective equipment, first aid measures and banned manners of handling the mixture.

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.