



77 ELEKTRONIKA KFT.

Product: **CRP, D-dimer, cTnI, HbA1c, hCG, TSH
mALB Rapid Test Kit**
According to Regulation (EU) No. 1907/2006
Revision date: 13-03-2023
Date of issue: 13-03-2023
Version: 2

Material Safety Data Sheet

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

1.1. Product identifier

Product name:	CRP Rapid Test Kit D-Dimer Rapid Test Kit cTnI Rapid Test Kit Hemoglobin A1c Rapid Test Kit hCG Rapid Test Kit TSH Rapid Test Kit mALB Rapid Test Kit
Product code / Catalog No. / REF:	RTC-9901-1, RTC-9905-1; RTC-9902-1, RCT-9906-1; RTC-9903-1, RTC-9907-1; RTC-9904-1, RTC-9908-1, RTC-9914-1; RTC-9913-1, RTC-9916-1; RTC-9910-1, RTC-9912-1; RTC-9909-1, RTC-9911-1, RTC-9918-1

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

1.2.1. Relevant identified uses:

Use of substance / mixture: | In vitro diagnostic. For professional use only.

1.2.2. Uses advised against:

Uses advised against: | No additional information available.

1.3. Details of supplier of the safety data sheet

Company name:	77 Elektronika KFT
Company address:	1116, Budapest, Fehérvári út 98., Hungary
Technical telephone:	+36-1-2061480
Fax:	+36-1-2061481
E-mail:	sales@e77.hu
Internet:	www.e77.hu

1.4. Emergency telephone number

Emergency number:	During working hours (CET: 8:00-- 16:35) +36-1-2061480 (in Hungarian, English and German languages) ugyfelszolgalat@e77.hu (in Hungarian, English and German languages)
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2. Hazards Identification

Warnings: | The usual precautions taken when handling chemicals should be observed.

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP):	This product holds no significant risks for human beings and environment.
Signal word (CLP):	This product holds no significant risks for human beings and environment.
Hazard statements (CLP):	This product holds no significant risks for human beings and environment.
Precautionary statements (CLP):	This product holds no significant risks for human beings and environment.

2.3. Other hazards

Other hazards: | No additional information available.

3. Composition, information on ingredients

3.1. Substance

Substance: | Not applicable.



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3.2. Mixture

Contains:	25 pcs. per box (CRP, D-dimer, cTnI, HbA1c, hCG, TSH, mALB) 5 pcs. per box (HbA1c)
Chemical characterization:	Test cassettes for CRP, D-dimer, cTnI, HbA1c, hCG, TSH, mALB parameters
Classification:	This mixture is not classified as dangerous according to Regulation (EC) No. 1907/2006.

3.3. Specific concentration limits:

No hazardous components.

4. First aid measures

4.1. Description of first aid measures

General information:	No administration in cases of unconsciousness or cramps. Move victim out of danger zone.
First aid measures general:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First aid measures after inhalation:	Provide fresh air. When symptoms occur go into open air and ventilate suspected area
First aid measures after skin contact:	After contact with skin, wash immediately with water. Remove contaminated clothing. Drench affected area with water for at least 15 minutes.
First aid measures after eye contact:	Rinse immediately carefully and thoroughly with eye-bath or water. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
First aid measures after ingestion:	Rinse mouth thoroughly with water. Consult physician immediately. Rinse mouth. Do NOT induce vomiting.
General advice:	Show this safety data sheet to the doctor in attendance.
Advice to doctor:	Do not leave the victim unattended. Treat symptomatically.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms / injuries:	May cause an allergic reaction in sensitive individuals.
Symptoms / injuries after inhalation:	Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms / injuries after skin contact:	May cause sensitization of susceptible persons by skin contact.
Symptoms / injuries after eye contact:	May cause eye irritation.
Symptoms / injuries after ingestion:	If a large quantity has ingested: May cause nausea, vomiting and diarrhea.
Chronic symptoms:	None expected under anticipated conditions of normal use.

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

If medical advice is needed, have product container or label at hand.

5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media:	Extinguishing materials should be selected according to the surrounding area. Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray, fog.
Extinguishing media which must be used for safety reasons:	No restriction. None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	Not flammable.
Explosion hazard:	Product is not explosive.
Reactivity:	Hazardous reactions will not occur under normal conditions.
Combustion products, resulting gases:	No risks worthy of mention.

5.3. Advice for firefighters

Firefighting instructions:	Exercise caution when fighting any chemical fire.
Protection during firefighting:	In case of fire wear self-contained breathing apparatus. Do not enter fire area without proper protective equipment, including respiratory protection.



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6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Refer to chapter 7 No further action is necessary.

6.1.1. For non-emergency personnel

Protective equipment:	Use appropriate personal protection equipment (PPE).
Emergency procedures:	Evacuate unnecessary personnel.

6.1.2. For emergency personnel

Protective equipment:	Equip clean crew with proper protection.
Emergency procedures:	Ventilate area.

6.2. Environmental precautions

Prevent entry to sewer and public waters.
Do not empty into drains of the aquatic environment.
Prevent spreading over great surfaces (e.g. by damming or installing oil booms).

6.3. Methods and material for containment and cleaning up

For containment:	Absorb and/or contain spill with inert material, then place in suitable container.
Methods for cleaning up:	Do not allow to enter into soil/subsoil. Collect mechanically. Treat the assimilated material according to the section on waste disposal. Clean up skills immediately and dispose of waste safely.

6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection.

7. Handling and storage

7.1. Precautions for safe handling

Handling:	Observe instruction for use.
Advice on safe handling:	No special precautionary measures are necessary.
Hygiene measures:	Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and again when leaving work.
Advice on protection against fire and explosion:	No special measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions:	Keep container dry. Keep container tightly closed.
Further information on storage conditions:	Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Recommended storage temperature: +4°C ÷ 30°C (CRP, D-dimer, cTnI, HbA1c, TSH, mALB) Recommended storage temperature: +1°C ÷ 30°C (hCG) Protect against heat
Storage class (D):	10-13
Incompatible products:	Strong acids. Strong bases. Strong oxidizers.

7.3. Specific end use(s)

Laboratory Material. For professional use only.

8. Exposure controls, personal protection

8.1. Control parameters

Not applicable.

8.2. Exposure controls

Appropriate Engineering Controls:	Wash hands before breaks and at the end of the work.
Protective and hygiene measures:	Wash hands before breaks and at the end of the work. When using do not eat or drink.
Personal Protective Equipment:	Protective goggles. Gloves. Protective clothing.
Materials for Protective Clothing:	Chemically resistant fabrics and materials



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Hand protection:	Tested protective gloves are to be worn: German Industry Norms (DIN) / European Norms (EN): EN 374 Breakthrough times and swelling characteristics of the material must be taken into consideration.
Eye protection:	Eye protection: tightly sealed safety glasses (safety glasses are not necessary)
Skin and Body Protection:	Suitable protection of the body: Lab apron. Footwear: Chemical resistant safety shoes.
Respiratory protection:	Respiratory protection not required.
Other Information:	When using do not eat, drink or smoke.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Solid.
Colour:	White.
Odour:	Not appropriate.
Odour threshold:	No information available.
Physical properties:	Not characterized.
pH:	Not appropriate.
Evaporation rate:	No information available.
Melting point:	No information available.
Freezing point:	No information available.
Boiling point:	No information available.
Flash-point:	Not determined.
Auto-ignition temperature:	No information available.
Decomposition temperature:	No information available.
Flammability (solid, gas):	No information available.
Vapour pressure:	No information available.
Relative vapour density at 20 °C:	No information available.
Solubility:	Insoluble.
Relative density:	No information available.
Partition coefficient: n-octanol/water	No information available.
Viscosity:	No information available.
Explosive properties:	No information available.
Oxidising properties:	No information available.
Explosive limits:	No information available.

9.2. Other information

No additional information available.

10. Stability and reactivity

10.1. Reactivity

Hazardous reactions will not occur under normal conditions. (Not by usage according to the instructions.)

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur under normal conditions.

10.4. Conditions to avoid

Decomposition possible after prolonged exposure to light. Direct sunlight. Extremely high or low temperature.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

The product is not flammable. However, under fire conditions, decomposition may produce carbon dioxide, carbon monoxide and nitrogen oxides (NOx).



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11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity:	No information available.
Skin corrosion/irritation:	No information available
Serious eye damage/irritation:	No information available.
Respiratory or skin sensitization:	No information available.
Germ cell mutagenicity:	No information available.
Carcinogenicity:	No information available
Reproductive toxicity:	No information available.
Specific target organ toxicity (single exposure):	No information available.
Specific target organ toxicity (repeated or prolonged exposure):	No information available.
Aspiration hazards:	No information available.
Symptoms/injuries after inhalation:	Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms/injuries after skin contact:	May cause sensitization of susceptible persons by skin contact.
Symptoms/injuries after eye contact:	May cause sensitization of susceptible persons by eye contact.
Symptoms/injuries after ingestion:	If a large quantity has been ingested. May cause nausea or vomiting.
Chronic symptoms:	None expected under anticipated conditions of normal use.
Specific effects in experiment on an animal:	No information available
Additional information on tests:	The classification was undertaken in accordance with the calculation method governed by the Preparations Directive (1999/45/EC)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No information available

11.2.2. Other information

No information available

12. Ecological information

12.1. Toxicity

Hazards:	Substance slightly hazardous to water and ground water.
Ecotoxicity:	No information available
LC50 fish 1:	No information available.
EC50 Daphnia 1:	No information available.
LC50 fish 2:	No information available.

12.2. Persistence and degradability

Persistence and degradability:	Product has not been tested. No information available. Not established.
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12.3. Bioaccumulative potential

Bioaccumulative potential:	Product has not been tested. No information available. Not established.
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12.4. Mobility in soil

No additional information available.

12.5. Results of PBT and vPvB assessment

No additional information available.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effect:

Other information:	Avoid release to the environment. The classification was undertaken in accordance with the calculation method governed by the Preparations Directive (1999/45/EC).
Other adverse effects:	Product has not been tested.



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13. Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations:

Advice on disposal:

Waste disposal number of waste from residual/unused products (160506):

Waste disposal number of used product (160506):

Waste disposal number of contaminated packaging (160506):

Contaminated packaging:

Dispose of waste material in accordance with all local, regional, national and international regulations.

Waste disposal according to official state regulations.

WASTES NOT OTHERWISE SPECIFIED IN THE LIST, gases in pressure containers and discarded chemicals, laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals.
Classified as hazardous waste.

WASTES NOT OTHERWISE SPECIFIED IN THE LIST, gases in pressure containers and discarded chemicals, laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals.
Classified as hazardous waste.

WASTES NOT OTHERWISE SPECIFIED IN THE LIST, gases in pressure containers and discarded chemicals, laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals.
Classified as hazardous waste.

Water (with cleaning agent). Completely emptied packings can be re-cycled.

14. Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	RID	IMDG	IATA	ADN
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the environment: NO	Dangerous for the environment: NO	Dangerous for the environment: NO Marine pollutant: NO	Dangerous for the environment: NO	Dangerous for the environment: NO

14.6. Special precautions for user(s)

No additional information available.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

Land transport (RID/ADR):

Inland waterways transport:

Marine transport:

Air transport:

Notation for shipping indication:

Notes:

Other applicable information not restricted.

Other applicable information not restricted.

Other applicable information not restricted.

Other applicable information not restricted.

Diagnosticum.

Is not subject to current regulations for transportation of hazardous goods.

15. Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions.



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Contains no substances on the REACH candidate list.
Contains no REACH Annex XIV substances.

15.1.2. National regulations

No additional information available.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.
This product has no identification liability in accordance with EC Directives 67/548 and 88/379.

16. Other information

Data sources: | According to Regulation (EU) No. 1907/2006.

Abbreviations and acronyms

ADR	Accord europeen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG	International Maritime Code for Dangerous Goods
IATA	International Air Transport Association
GHS	Globally Harmonized System of Classification and Labelling of Chemical
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
CAS	Chemical Abstracts Service
LC50	Lethal concentration, 50%
LD50	Lethal dose, 50%

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

The information herein is believed to be correct as the data hereof but does purport to be all inclusive and shall be used only as a guide.
77 Elektronika Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product. The recipient of our product is responsible for ensuring that where applicable, existing laws and guidelines are observed.