

SAFETY INFORMATION

PRODUCT: HEV AB Version ULTRA Elisa

CODES (REF): KAPDEVABULTRA

The product **HEV Ab Version ULTRA** is an Enzyme Immuno Assay (ELISA for the qualitative determination of total antibodies to Hepatitis E Virus (HEV) in serum and plasma. The kit is intended for the follow-up of HEV-infected patients and the screening of blood units. In addition, due to the assay configuration of the product, the kit may be used also in testing total antibodies to HEV in serum and plasma derived from other not-human recipients for zoonotic studies. For "in vitro" diagnostic use.

Each kit is composed of:

MICROPLATE

MICROPLATE 12 strips of 8 breakable wells. Microplates are coated with HEV highly specific synthetic antigen.

The substance is not classified as dangerous according to the Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according the EC regulation 1907/2006 and 453/2010, is not necessary to develop a Material Safety Data Sheet.

CONTROL -

NEGATIVE CONTROL

The substance is not classified as dangerous according to the Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according the EC regulation 1907/2006 and 453/2010, is not necessary to develop a Material Safety Data Sheet

Contents: Bovine carrier proteins, 10 mM phosphate buffer pH 7.4 ± 0.1, 0.09% sodium azide and 0.045% ProClin 300.

CONTROL +

POSITIVE CONTROL

The substance is not classified as dangerous according to the Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according the EC regulation 1907/2006 and 453/2010, is not necessary to develop a Material Safety Data Sheet

Contents: Bovine carrier proteins, 10mM phosphate buffer pH 7.4 ± 0.1, inactivated human serum positive to HEV Ab and negative for HBsAg, HIV, Syphilis and HCV markers, 0.09% sodium azide and 0.045% ProClin 300.

CAL....

CALIBRATOR

The substance is not classified as dangerous according to the Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according the EC regulation 1907/2006 and 453/2010, is not necessary to develop a Material Safety Data Sheet

Contents: Fetal bovine serum proteins, human antibodies to HEV whose content is calibrated on 1st WHO reference reagent for HEV antibody, at 1 IU/ml ± 20%, 10 mM Na-citrate buffer pH 6.0 ± 0.1, 0.3 mg/ml gentamicine sulphate and 0.045% ProClin 300 as preservatives.

WASH BUF 20x

WASH BUFFER CONCENTRATE

The substance is not classified as dangerous according to the Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according the EC regulation 1907/2006 and 453/2010, is not necessary to develop a Material Safety Data Sheet

Contents: Once diluted, the wash solution contains 10 mM phosphate buffer pH 7.0 ± 0.2, 0.05% Tween 20 and 0.045% ProClin 300.

CONJ

ENZYME CONJUGATE

The substance is not classified as dangerous according to the Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according the EC regulation 1907/2006 and 453/2010, is not necessary to develop a Material Safety Data Sheet.

Contents: HEV specific synthetic antigen, labeled with HRP, 5% BSA, 10 mM Tris buffer pH 6.8 ± 0.1, 0.3 mg/ml gentamicine sulphate and 0.045% ProClin 300 as preservatives

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SUBS TMB

CHROMOGEN/SUBSTRATE

The substance is not classified as dangerous according to the Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according the EC regulation 1907/2006 and 453/2010, is not necessary to develop a Material Safety Data Sheet.

Contents: 50 mM citrate-phosphate buffer pH 3.5-3.8, 4% dimethylsulphoxide, 0.03% tetra-methyl-benzidine or TMB and 0.02% hydrogen peroxide or H₂O₂.

H₂SO₄ 0.3 M

SULPHURIC ACID

The substance is classified as **irritant** according to regulation 1272/2008/CE and European Directive 1999/45/CE. The Material Safety Data Sheet, prepared in accordance with EC regulations 1907/2006 e 453/2010 is available below

Contents: 0.3 M H₂SO₄ solution.

SAFETY DATA SHEET

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

- 1.1. Product identifier:
H2SO4 0.3 M
- 1.2. Relevant identified uses of the mixture and uses advised against:
Stop solution for the Elisa kits listed in 1.1 for professional use.
- 1.3. Details of the supplier of the safety data sheet:
Dia.Pro Diagnostic Bioprobes Srl
Via G. Carducci n°27
20099 Sesto San Giovanni (Mi) - Italy
Tel.:+39 02 27007161
Fax.:+39 02 44386771
- 1.4 1.4. Emergency telephone number: +39 02 27007161

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. Classification of the mixture:
- Classification according to Regulation 1272/2008/EC (CLP):
Eye Irrit. 2 – H319
Skin Irrit. 2 – H315

Warning H statements:

H315 – Causes skin irritation.

H319 – Causes serious eye irritation.

Classification according to Directive 1999/45/EC:
Xi – Irritant – R 36/38

R phrases referring to the hazards/risks:

R 36/38 - Irritating to eyes and skin.

- 2.2. Label elements:

Components which define the hazards: none.

GHS07



WARNING

Warning H statements:

H315 – Causes skin irritation.

H319 – Causes serious eye irritation.

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Precautionary P statements:

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352 – IF ON SKIN: 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.

P337 + P313 – If eye irritation persists: Get medical advice/attention.

P362 + P363 – Take off contaminated clothing and wash it before reuse.

2.3. Other hazards:

Risk for health/environment: a harmful effect on aquatic organism cannot be excluded in the event of the improper handling or disposal. Harmful effect due to pH shift.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance:

Not applicable.

3.2. Mixture: Aqueous solution; Concentration of the substance in the preparation: 3% (w/w)

Dangerous components:							
Description	CAS number	EC number	Classification				
			67/548/EEC		1272/2008/EC (CLP)		
			Hazard symbol	R phrase	Hazard pict.	Hazard cat.	H phrase
Sulphuric acid	7664-93-9	231-639-5	C	35	GHS05 Dgr	Skin Corr. 1A	H314

For the full text of R and H phrases: see Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures:

IN CASE OF INGESTION:

Measures:

- Wash out mouth thoroughly with water, avoid vomiting if possible.
- Call a physician immediately.
- Do not attempt to neutralize.

IN CASE OF INHALATION:

Measures:

- Remove from exposure.
- Fresh air.

IN CASE OF SKIN CONTACT:

Measures:

- Immediately remove contaminated clothing.
- Wash immediately with plenty of water.
- Call a physician in the event of irritation.

IN CASE OF EYE CONTACT:

Measures:

- Irrigate thoroughly with water for at least 10 minutes.
- Consult a physician.

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

No data available.

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

No data available.

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SECTION 5: FIRE-FIGHTING MEASURES

- 5.1. Extinguishing media:
- 5.1.1. Suitable extinguishing media:
The mixture does not burn. Use CO₂, not H₂O₂.
- 5.1.2. Unsuitable extinguishing media:
None known.
- 5.2. Special hazards arising from the substance or mixture:
The reaction with reducing agents generate heat.
With nitrates, chlorates, carbides, potassium permanganate, powdered metals can causes fire and explosion. With sulphides releases H₂S, a toxic and flammable gas.
- 5.3. Advice for firefighters:
Wear full protective clothing and self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1. Personal precautions, protective equipment and emergency procedures:
- 6.1.1. For non-emergency personnel:
Keep unprotected people away, allow only well trained experts wearing suitable protective clothing to abide in the field of accident.
- 6.1.2. For emergency responders:
Wear personal and appropriate protection articles. Avoid substance contact with skin, eyes and clothes.
- 6.2. Environmental precautions:
Dispose of spillage and waste (product/packaging) in accordance with all applicable environmental laws. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.
- 6.3. Methods and material for containment and cleaning up:
Take up with liquid-absorbent inert material. Neutralize with diluted sodium hydroxide solution or with lime milk and rinse with plenty of water.
- 6.4. Reference to other sections:
For further and detailed information see section 8 and 13.

SECTION 7: HANDLING AND STORAGE

- 7.1. Precautions for safe handling:
Observe conventional hygiene precautions.
Handle according to good industrial hygiene and safety practices for diagnostic products.
Technical measures:
Ensure adequate ventilation.
Precautions against fire and explosion:
No special measures required.
- 7.2. Conditions for safe storage, including any incompatibilities:
Technical measures and storage condition:
Store in the original container at 2°- 8°C.
Incompatible materials: Reducing agents, nitrates, picrates, carbides, chlorates, permanganates, powdered metals, alkali metals, alkali compounds.
Packaging material: no special prescriptions.
- 7.3. Specific end use(s):
No specific instructions available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1. Control parameters:
- Exposure limit values (2000/39/EC, 2006/15/EC, 2009/161/EU):
- The components of the mixture are not regulated with exposure limit value.

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DNEL		Routes of exposure	Exposure frequency:	Remarks:
Worker	Consumer			
no data available	no data available	Dermal	Short term (acute) Long term (repeated)	no data available
no data available	no data available	Inhalative	Short term (acute) Long term (repeated)	no data available
no data available	no data available	Oral	Short term (acute) Long term (repeated)	no data available

PNEC			Exposure frequency:	Remarks:
Water	Soil	Air		
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available

8.2. Exposure controls:

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.2.1 Appropriate engineering controls:

In pursuance of work is proper foresight needed to avoid leaking onto clothes and floors and to avoid contact with eyes and skin. Observe general industrial hygiene practices.

8.2.2. Individual protection measures, such as personal protective equipment:

1. Eye/face protection: use appropriate safety glasses (EN 166).
2. Skin protection:
 - a. Hand protection: use appropriate protective gloves made of latex or rubber (EN 374).
 - b. Other: use acid resistant lab coats.

3. Respiratory protection: not required.

4. Thermal hazard: none known.

8.2.3. Environmental exposure controls:

No special measures required.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions an expert's advice should be sought out before deciding upon further protective measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Parameter		Test method:	Remarks:
1. Appearance:	colourless liquid		
2. Odour:	odourless		
3. Odour threshold:	no data available		
4. pH value:	< 1	20 °C	
5. Melting point/freezing point:	- 11 °C		
6. Initial boiling point/boiling range:	100°C		
7. Flash point:	not applicable		
8. Evaporation rate:	no data available		
9. Flammability:	not applicable		
10. Upper/lower flammability or explosive limits:	no data available		
11. Vapour pressure:	not applicable		
12 Vapour density:	no data available		
13. Relative density:	1 – 1,03		
14. Solubility(ies):	soluble in water		
15. Partition coefficient: n-octanol/water:	no data available		

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16. Self-ignition temperature: not applicable
17. Degradation temperature: no data available
18. Viscosity: no data available
19. Explosive properties: not applicable
20. Oxidizing properties: not applicable
- 9.2. Other information:
No data available.

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:
None known.
- 10.2. Chemical stability:
This mixture is stable under normal condition
- 10.3. Possibility of hazardous reactions:
None known.
- 10.4. Conditions to avoid:
None known.
- 10.5. Incompatible materials:
Reducing agents, nitrates, picrates, carbides, chlorates, permanganates, powdered metals, alkali metals, alkali compounds.
- 10.6. Hazardous decomposition products:
In the event of fire: see Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. Information on toxicological effects:
Acute toxicity: none known.
Skin corrosion/irritation: causes skin irritation.
Serious eye damage/eye irritation: causes serious eye irritation.
Respiratory or skin sensitisation: none known.
Germ cell mutagenicity: none known.
Carcinogenicity: none known.
Reproductive toxicity: none known.
STOT-single exposure: none known.
STOT-repeated exposure: none known.
Aspiration hazard: none known.
- 11.1.1. For substances subject to registration, brief summaries of the information derived from the test conducted:
No data available.
- 11.1.2. Relevant toxicological properties of the hazardous substances:
No data available for the mixture.
Acute toxicity of the pure substance (Sulphuric acid):
LC50 (inhalation, rat): 510 mg/m³/2h
LD50 (inhalation, rat): 2140 mg/kg
Local effect of substance (Sulphuric acid):
Highly corrosive and necrotizing on tissues.
The ingestion generates burns on the upper digestive system and the respiratory tract.
- 11.1.3. Information on likely routes of exposure:
Ingestion, inhalation, skin contact, eye contact.
- 11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:
No data available.
- 11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:
Causes skin irritation.
Causes serious eye irritation.
- 11.1.6. Interactive effects:
No data available.
- 11.1.7. Absence of specific data:
No information.
- 11.1.8. Other information:
No data available.

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SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity:
Use mixture according to good laboratory practice and avoid the dispersion in the environment.
A harmful effect on aquatic organism cannot be excluded in the event of the improper handling or disposal. Harmful effect due to pH shift.
- 12.2. Persistence and degradability:
No data available.
- 12.3. Bioaccumulation potential:
No data available.
- 12.4. Mobility in soil:
No data available.
- 12.5. Results of PBT and vPvB assessment:
No data available.
- 12.6. Other adverse effects:
No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods:
Disposal according to the local regulations.
- 13.1.1. Information regarding the disposal of the product:
Chemical residues are general classified as special waste, and as such are covered by regulation which vary according to location. Contact your local waste disposal authority for advice, or pass to a chemical disposal company. The disposal of liquid effluent should be carried out according to the existing local laws and to the existing local regulation governing local pollution.
European Waste Code:
For this product no waste disposal key according the European Waste Catalogue (EWC) can be determined, as only the purpose of application defined by the user enables an allocation. The European waste code number has to be determined after a discussion with a specialist dealing with waste disposal.
- 13.1.2. Information regarding the disposal of the packaging:
Dispose according to the relevant regulations.
- 13.1.3. Physical/chemical properties that may affect waste treatment options shall be specified:
None known.
- 13.1.4. Sewage disposal:
None known.
- 13.1.5. Special precautions for any recommended waste treatment:
No data available.

SECTION 14: TRANSPORT INFORMATION

Not dangerous good in sense of the transport regulations.

- 14.1. UN Number:
None.
- 14.2. UN proper shipping name:
None.
- 14.3. Transport hazard class(es):
None.
- 14.4. Packaging group:
None.
- 14.5. Environmental hazard:
No relevant information available.
- 14.6. Special precautions for user:
No relevant information available.
- 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
Not applicable.

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SECTION 15: REGULATORY INFORMATION

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

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

DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

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

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

15.2. Chemical safety assessment: no information available.

SECTION 16: OTHER INFORMATION

Information regarding the revision of the safety data sheet:

The safety data sheet has been revised according to Regulation 453/2010/EU (Section 1-16).

The classification of the components and the mixture have been amended according to Regulation 1272/2008/EC (CLP) and its amendments.

Full text of the abbreviations in the safety data sheet:

DNEL: Derived no effect level. PNEC: Predicted no effect concentration. CMR effects: carcinogenicity, mutagenicity and toxicity for reproduction. PBT: Persistent, bioaccumulative and toxic. vPvB: Very Persistent, Very Bioaccumulative. n.d.: not defined. n.a.: not applicable.

Key literature references and sources for data: previous version of safety data sheet (January 2004) issued by the manufacturer.

Relevant R-Phrases (number and full text) of Section 2 and 3:

R 35 - Causes severe burns.

R 36/38 - Irritating to eyes and skin.

Relevant H-Phrases (number and full text) of Section 2 and 3:

H314 – Causes severe skin burns and eye damage.

H315 – Causes skin irritation.

H319 – Causes serious eye irritation.

Training advice: no data available.

This safety data sheet had been prepared on the basis of information provided by the manufacturer/supplier and conform to the relevant regulations. The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information. The SDS shall be used only as a guide for handling the product; in the course of handling and using the product other considerations may arise or be required. Users are cautioned to determine the appropriateness and applicability of the above information to their particular circumstances and purposes and assume all risk associated with the use of this product. It is the responsibility of the user to fully comply with local, national and international regulations concerning the use of this product.