

<b>1. Identification of substance</b>	
REF / Article Number	3115
Name of Product	ANA-HEp-2
Manufacturer / Supplier	<b>AESKU.DIAGNOSTICS GmbH &amp; Co. KG</b> Mikroforum Ring 2 55234 Wendelsheim Germany Tel.: +49-6734-9622-0 Fax: +49-6734-9622-2222 E-mail: info@aesku.com http: www.aesku.com

<b>2. Hazard information</b>	
2.1 Classification of the substances or mixture Product is <b>not classified as hazardous</b> according to the European Regulation 1999/45/EC or 1272/2008/EC. Human health hazards: No specific hazard.	
2.2 Label Elements	
Pictogram	None
Signal Word	None
Hazard Statement(s)	None
Precautionary Statement(s)	None
Supplement Hazard Statement(s)	None
2.3 Other Hazards None	

<b>3. Composition / Data on components</b>	
Coated microplate:	Purified antigen coated onto polystyrene microwells.
Calibrators / Controls:	Calibrator/control material <1% in phosphate buffered saline with Tween 20 as detergent, sodium azide 0.09% as preservative and BSA for stabilization.
Enzyme conjugate:	Peroxidase conjugated antibodies <0.0001% in phosphate buffered saline and bovine serum albumin (BSA) for stabilization.
Sample buffer (5x):	Phosphate buffered saline with sodium azide 0.09% as preservative and BSA for stabilization.
Wash buffer (50x):	Tris buffered saline with Tween 20 as detergent and sodium azide 0.09% as preservative.
Substrate solution:	Aqueous solution of TMB (3,3',5,5'-Tetramethylbenzidin) 0.04% and H <sub>2</sub> O <sub>2</sub> < 0.01%. ProClin 300 <0.0001% as preservative.
Stop solution:	Aqueous solution of hydrochloric acid 3%.

The bovine serum albumin was derived from bovine blood collected at USDA licensed establishment. Even though all mixtures do not meet the criteria for classification according to 1272/2008/EC we have summarized the components below for reason of completeness:

EINECS	CAS-No.	name	%	symbol	H-statements
<b>Wash buffer</b>					
247-852-1	26628-22-8	Sodium azide	<0.1		H300, H400, H410
201-064-4	77-86-1	Tris(hydroxymethyl)-aminomethan	<0.9		H315, H319
<b>Calibrators / Controls / Enzyme conjugate / Sample buffer</b>					
247-852-1	26628-22-8	Sodium azide	<0.1		H300, H400, H410
<b>Substrate</b>					
259-364-6	54827-17-7	3,3',5,5'-Tetramethylbenzidine	<0.04		H301, H311, H330, H341
247-500-7	26172-55-4	5-Chlor-2-methyl-4-isothiazolin-3-on	<0.01		H272, H314, H317, H334
220-239-6	2682-20-4	2-Methyl-4-isothiazolin-3-on	<0.01		H272, H314, H317, H334
231-765-0	7722-84-1	Hydrogen peroxide	<0.005		H302, H318
<b>Stop Solution</b>					
231-595-7	7647-01-0	Hydrochlorid acid	<3.0		H290
The full text of H-statements is in article 16					

#### 4. First aid measures

##### 4.1 Description of First Aid measures

<b>General information</b>	Consult a physician. Show this safety data sheet to the doctor in attendance.
<b>After inhalation</b>	If breathed in, move the concerned person into fresh air. In case of apnoea, give artificial respiration. Consult a physician.
<b>After skin contact</b>	Wash off with plenty of water. Consult a physician.
<b>After eye contact</b>	Rinse the opened eye for several minutes with running water, if necessary remove contact lenses. Consult an ophthalmologist.
<b>After swallowing</b>	Never give anything by mouth to an unconscious person. Rinse mouth with water, drink sufficient amount of water, 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

#### 5. Fire fighting measures

##### 5.1 Extinguishing media

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

##### 5.2 Special Hazards arising from the substance or mixture

The product itself is not inflammable; extinguishing measures should therefore be prepared for an environmental fire. In case of fire toxic vapors, e.g. nitric oxide, can be released.

##### 5.3 Advice for fire fighters

Wear breath protective mask and protective clothes if necessary during fire fighting.

<b>6. Accidental release measure</b>	
Person-related safety precautions	Use personal protective equipment. Avoid breathing vapor/mist/gas. Care for appropriate ventilation.
Measures for environmental protection	Prevent seepage into sewage system, workpits and cellars. Do not allow to enter sewers/ surface or ground water.
Measures for cleaning/collecting	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13.
Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.	

<b>7. Handling and storage</b>	
Handling:	Special measures are not required.
Storage:	Store at 2 to 8 °C. Protect from light.

<b>8. Exposure controls and personal protection gear</b>	
Respiratory protection:	Not required.
Hand protection:	Wear protective gloves of nitril rubber or nature latex.
Eye protection:	Wear protective glasses.

<b>9. Physical and chemical properties</b>	
Coated microplate:	Polystyrol microwells in foil pouch.
Calibrators:	Yellow fluid in polyethylene bottle.
Enzyme conjugate:	Red (IgA), Blue (IgG), Green (IgM) fluid in polyethylene bottle.
Sample buffer:	Yellow fluid in polyethylene bottle.
Wash buffer:	Green fluid in polyethylene bottle.
Substrate solution:	Colorless fluid in polyethylene bottle.
Stop solution:	Colorless fluid in polyethylene bottle.

<b>10. Stability and reactivity</b>	
10.1. Reactivity No data available.	
10.2 Chemical stability No data available.	
10.3 Possibility of hazardous reactions No data available.	
10.4 Conditions to avoid Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the product).	
10.5 Incompatible materials Oxidizing agents, metals (will not cause a dangerous reaction, but destroys the quality of the product).	
10.6 Hazardous decomposition products Dangerous decomposition products are not known.	

<b>11. Toxicological information</b>	
Used according to intended use no toxicological reactions known.	

## 12. Ecological information

Used according to intended use no ecological reactions known.

## 13. Disposal considerations

Waste should be disposed of in accordance with federal, state and local environmental control regulations. When disposing of conjugate solution, sample buffer or wash buffer flush drains with copious amounts of water. Disposal of packaging according to the instructions of the public authorities.

## 14. Transport information

This product is not subject to official transport regulations.

## 15. Regulations

1907/2006/EC	Registration, evaluation and authorization of chemicals regulation (REACH)
1272/2008/EC	Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EWG and 1999/45/EC, amending 1907/2006/EC
453/2010/EC	Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC
This product is not classified according to the EU regulations 1272/2008. No labeling requirement.	

## 16. Other information

Revision according to 453/2010 EU.

All mixtures do not meet the criteria for classification according to 1272/2008/EC.

Safety data for product including all components. This product is intended for professional laboratory use. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### Full text to the H-statements mentioned in heading 3:

H272 May intensify fire; oxidiser.  
H290 May be corrosive to metals.  
H300 Fatal if swallowed.  
H301 Toxic if swallowed.  
H302 Harmful if swallowed.  
H311 Toxic in contact with skin.  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H330 Fatal if inhaled.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H341 Suspected of causing genetic defects.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

The REACH registration numbers is not available as the substances or its use is exempted from registration according to article 2 REACH Regulation EC 1907/2006, or the annual tonnage does not require a registration and is envisaged for a later registration deadline.

### **Department issuing MSDS**

Quality control

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