

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**1.1 Product identifier**

Product Name: Malaria Ab ELISA

Catalog #: KAPDMA

Kit Components: Microplate
Controls
Calibrattor
Wash buffer
Conjugates
Conjugate diluent
Substrate
Stop Solution
Sample Diluent**1.2 Intended Use**

In vitro diagnostic use. For professional use.

1.3 CompanyDIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: products.support@diasource.be**1.4 Emergency telephone**DIAsource (only office hours): +32 (0)10/84.99.11
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!**2 HAZARDS IDENTIFICATION****2.1 Classification of the substance or 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

Stop Solution



Danger

 Warning **H statements**:

H315 – Causes skin irritation.

 Precautionary **P statements**:

P260 – Do not breathe dust/fumes/gas/mist/vapours/spray.

P264 – Wash ... thoroughly after handling.

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

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.

3 COMPOSITION/INFORMATION ON INGREDIENTS

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 Danger	Skin Corr. 1A	H314

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

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.

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.

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/package) 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.

7 HANDLING AND STORAGE
7.1 Precautions for safe handling

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.

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.

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 (acute) Long term (continuous)	No data available
No data available	No data available	No data available	Short term (acute) Long term (continuous)	No data available
No data available	No data available	No data available	Short term (acute) 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.

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:	20°C	< 1
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
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.

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.

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.

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.

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.

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.

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.

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:

H315 – Causes skin 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.

MSDS established : 2023-12-14

Revision number : 2