

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

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|-----|----------------|--|
| 1.1 | Product name | DIASOURCE E2 ELISA kit |
| | Catalog # | KAP0621 |
| | Kit components | Microtiter plate
Antiserum
Calibrator 0
Calibrators 1 to 5
Estradiol-HRP Conjugate
Conjugate Buffer
Controls 1 and 2
Washing Solution
Substrate Buffer
Chromogen TMB
Stop Solution |
| 1.2 | Intended Use | In vitro diagnostic use |
| 1.3 | Company | DIAsource 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 | In emergencies | Call your local emergency centre |

2. HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture:****2.1.1 Classification according to Regulation (EC) no 1272/2008 (CLP)****Calibrators 0-5 and Controls**

Skin sensitisation CAT 1

Stop Solution

Skin irritation 2

Chromogen TMB

Repro. 1B

Acute toxicity 4

Eye irritation 2

2.1.2 Classification according to Directive 1999/45/EC**Stop Solution**

Irritation

Chromogen TMB

Irritation, harmful

2.1.3 Additional Information**Chromogen TMB**

Flammable liquids (Category 3)

2.2 Label elements:

Labeling according to Regulation (EC) no 1272/2008 (CLP)

Calibrator 0, calibrators 1-5 and ControlsH317
P280-P302+352-P333+313-P363

Danger

Stop SolutionH290-H314
P280-P301+330+331-P305+351+338-P308-310

Danger

Chromogen TMBH360D-H332-H312-H319-H226
P201-280-P305+351+338-P308+313

Danger

2.3 Other hazards:**Estradiol-HRP Conjugate, Conjugate Buffer, Antiserum**

Contains material from bovine origin.

Calibrator 0, Calibrators 1-5 and Controls 1 and 2

Contains material of human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

3. COMPOSITION/INFORMATION ON INGREDIENTS
Hazardous ingredients:

Component	Classification	concentration
Calibrator 0, calibrators 1-5 and Controls 1 and 2:		
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)		
CAS-No. 55965-84-9	Skin Sensitization CAT 1, H317	< 0,06%
Index-No. 613-167-00-5		
Stop Solution containing:		
Sulfuric acid		
CAS-No. 7664-93-9	Skin corrosion 1A, H314 Corrosive to metals 1, H290	< 10%
EC-No. 231-639-5		
Index-No. 016-020-00-8		
Chromogen TMB containing:		
Dimethylformamide		
CAS-No. 68-12-2	Flam. Liq. 3; Acute Tox. 4; Eye Irrit. 2; Repr. 1B; H226, H319, H312, H332, H360D, H226, H312 + H332, H319, H360	<= 100 %
EC-No. 200-679-5		
Index-No. 616-001-00-X		

4. FIRST AID MEASURES
4.1 Description of first aid measures
All Kit Components

- After skin contact:*
- Wash immediately with soap and plenty of water for at least 10 minutes.
 - Consult a physician.
- After eye contact:*
- Remove and wash contaminated clothing before re-use.
 - Wash immediately with plenty of water for at least 15 minutes.
 - Consult immediately a physician
- After ingestion:*
- Do NOT induce vomiting.
 - Never give anything by mouth to an unconscious person.
 - Rinse mouth with water.
 - Consult a physician.
- After inhalation:*
- Transfer the person to an open place.
 - If he does not breathe, proceed to artificial respiration or provide oxygen.
 - Consult a physician.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE FIGHTING MEASURES**Chromogen TMB, Stop Solution***Suitable extinguishing media:*

- Carbon dioxide, dry chemical powder or appropriate foam
- Do not use water

Unsuitable extinguishing media:

- No data available

Special exposure hazards:

- Strong dehydrating agent which may cause ignition of finely divided materials on contact. (only applies to stop solution)

- Emits toxic fumes under fire conditions

- Water reactive material (only applies to stop solution)

Instructions:

- Prevent contact with skin and eyes

Special protective equipment for firefighters:

- Wear self-contained breathing apparatus and protective clothing

Other Kit Components*Suitable extinguishing media:*

- All non combustible extinguishing media allowed

Unsuitable extinguishing media:

- No data available

Special exposure hazards:

- No generation of hazardous or toxic gases in dangerous quantities

Instructions:

- Due to small quantities: no special instructions apply

Special protective equipment for firefighters:

- Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.

6. ACCIDENTAL RELEASE MEASURES**All Kit Components***Personal protection:* see 8*Environmental precautions:*

- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:

- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

7. HANDLING AND STORAGE**All Kit Components***Handling:*

- Use only in a chemical fume hood (only applies to chromogen TMB, stop solution)
- Observe normal hygiene standards
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

Storage:

- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, combustible materials, acids, metals
- Storage temperature: see component label

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1 Control parameters
Components with workplace control parameters

Component	Country		mg/m ³
Sulfuric acid CAS 7664-93-9	Poland	NDS	1
		NDSch	3
		NDSP	-
	Denmark	OEL-TWA	1
	Germany	TRGS - OEL	1
	Norway	OEL	0.2
	Sweden	LLV	1
	Switzerland	OEL	1
	United Kingdom	OEL	1

Component	Country		mg/m ³
Dimethylformamide CAS 68-12-2	Poland	NDS	10
		NDSch	-
		NDSP	-
	Denmark	OEL-TWA	30
	Germany	TRGS - OEL	30
	Norway	OEL	30
	Sweden	LLV	30
	Switzerland	OEL	30
	United Kingdom	OEL	30
	STEL	61	

8.2 Exposure Controls
8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protection equipment
All Kit Components

- Eye protection:*
- Safety goggles (chromogen TMB, stop solution)
 - Face shield (other components)
 - Gloves
 - No data available
 - Protective clothing

9. PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties****Microtiter Plate:** plate**Controls 1 and 2, Calibrator 0, Calibrators 1 to 5:** Lyophilized, soluble in water**Washing Solution, Chromogen TMB, Conjugate Buffer, Stop Solution, Estradiol-HRP Conjugate, Antiserum, Substrate Buffer:** Liquid**9.2 Other Information**

No data available

10. STABILITY AND REACTIVITY**Chromogen TMB***Stability:* Stable until expiry date if stored in specified conditions (see label)*Reactivity/Hazardous decomposition products:* Thermal decomposition may produce carbon monoxide, carbon dioxide and nitrogen oxides.*Conditions/Materials to avoid:* Strong oxidizing agents**Stop Solution***Stability:* Stable until expiry date if stored in specified conditions (see label)*Reactivity/Hazardous decomposition products:* Sulfur oxides*Conditions/Materials to avoid:* Protect from moisture and strong oxidizing agents, do not allow water to enter the container and avoid contact with water.**Other Kit Components***Stability:* All components are stable until expiry date if stored in specified conditions (see label)*Reactivity/Hazardous decomposition products:* No hazardous decomposition products are formed in high quantities*Conditions/Materials to avoid:* None known**11. TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects****ProClin 300** (contains mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)):

Acute toxicity	No data available
Skin corrosion/irritation	Skin - rabbit - Corrosive
Serious eye damage/irritation	Eyes - rabbit - Corrosive to eyes
Respiratory or skin sensitization	May cause allergic skin reaction.
Germ cell mutagenicity	No data available
Carcinogenicity	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	No data available
STOT-single exposure	No data available
STOT-repeated exposure	No data available
Aspiration hazard	No data available
Potential Health effects	Inhalation Harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.



MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product name: DIASOURCE E2 ELISA kit

Catalog #: KAP0621

Ingestion Harmful if swallowed. Causes burns.
Skin May be harmful if absorbed through skin. Causes skin burns.
Eyes Causes eye burns.
Aggravated Medical Condition
May provoke asthmatic response in persons with asthma who are sensitive to airway irritants,

Additional information Not available.

Sulfuric acid:

Acute oral toxicity This information is not available.
Acute inhalation toxicity This information is not available.
Acute dermal toxicity This information is not available.
Skin irritation Causes severe burns.
Eye irritation Causes serious eye damage. Risk of blindness!
Sensitisation This information is not available.
Germ cell mutagenicity This information is not available.
Carcinogenicity This information is not available.
Reproductive toxicity This information is not available.
Teratogenicity This information is not available.
Specific target organ toxicity - single exposure This information is not available.
Specific target organ toxicity - repeated exposure This information is not available.
Aspiration hazard This information is not available.

Dimethylformamide:

Acute toxicity LD50 Oral - rat - 2.800 mg/kg
LC50 Inhalation - rat - 4 h - 9 - 15 mg/l
LD50 Dermal - rabbit - 1.500 mg/kg
Skin corrosion/irritation Skin - Human
Result: Mild skin irritation - 24 h
Serious eye damage/eye irritation Eyes - rabbit
Result: Moderate eye irritation
Respiratory or skin sensitization no data available
Germ cell mutagenicity mouse
lymphocyte
Mutation in mammalian somatic cells.
Carcinogenicity This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification.
IARC: 3 - Group 3: Not classifiable as to its carcinogenicity to humans (N,N-Dimethylformamide)
Reproductive toxicity May cause congenital malformation in the fetus.
Specific target organ toxicity - single exposure no data available
Specific target organ toxicity - repeated exposure no data available
Aspiration hazard no data available

12. ECOLOGICAL INFORMATION**12.1 Toxicity****Aquatic toxicity****Sulfuric acid:**

EC100 - Daphnia magna (Water flea) - 160 - 400 mg/l - 48 h

EC50 - Daphnia magna (Water flea) - 160 - 400 mg/l - 48 h

EC100 - Daphnia magna (Water flea) - 200 mg/l - 24 h

EC50 - Desmodesmus subspicatus (green algae) - 41 mg/l - 72 h

Dimethylformamide:

LC50 - Oncorhynchus mykiss (rainbow trout) - 9.000 - 13.000 mg/l - 96 h

LC50 - Lepomis macrochirus (Bluegill) - 6.700 - 7.500 mg/l - 96 h

LC50 - Pimephales promelas (fathead minnow) - 10.400 - 10.800 mg/l - 96 h

h

LC50 - Oncorhynchus mykiss (rainbow trout) - 9.800 mg/l - 96 h

LC50 - Lepomis macrochirus (Bluegill) - 6.300 mg/l - 96 h

LC50 - Pimephales promelas (fathead minnow) - 10.600 mg/l - 96 h

12.2 Persistence and degradability**Diméthylformamide:** Biodegradability Result: > 90 % - Readily biodegradable.**12.3 Bioaccumulative potential****Sulfuric acid:** Bioaccumulation Leuciscus idus melanotus - 3 d

- 31 µg/l

Bioconcentration factor (BCF): < 10

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment**ProClin® 350:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.**12.6 Other adverse effects****Sulfuric Acid:** Toxic to aquatic life with long lasting effects.**ProClin® 350:** An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.**13. DISPOSAL CONSIDERATIONS***Provisions relating to waste:* Hazardous waste (91/689/EEC)*Packaging/container:* Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)*Disposal methods:*

- Tested specimens, estradiol-HRP conjugate, antiserum, conjugate buffer, calibrator 0, calibrators 1 to 5, controls 1 and 2 are potentially infectious. They should be disposed of following established safety procedures and local regulations.
- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.

14. TRANSPORT INFORMATION

Not applicable

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the mixture

no data available

15.2 Chemical Safety assessment

no data available

16. OTHER INFORMATION**16.1 Indication of changes**

v1: SDS changes as required by current REACH regulation (as amended by 453/2010).
Classification and labeling according to CLP added.

16.2 Abbreviations and acronyms**16.3 Key literature references and sources for data**

SDS sheets provided by suppliers of raw materials.

16.4 Classification and procedure used to derive the classification for mixtures according to regulation EC 1272/2008 – CLP

Classification of mixtures is based on the calculation method.

16.5 Relevant H-P statements

H290 May be corrosive to metals

H312 Harmful in contact with skin

H314 Causes severe skin burns and eye damage

H315 Causes skin irritation

H317 May cause an allergic skin reaction

H319 Causes serious eye irritation

H360 May damage fertility or the unborn child

P201 Obtain special instructions before use

P264 Wash ... thoroughly after handling

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

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. DO NOT induce vomiting

P302+352 IF ON SKIN: Wash with plenty of soap and water

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 IF exposed or concerned: Get medical advice/attention

P309+310 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician

P321 Specific treatment

P332 + P313 If skin irritation occurs: Get medical advice/attention



MATERIAL SAFETY DATA SHEET

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P333+313 If skin irritation or rash occurs: Get medical advice/attention

P362 Take off contaminated clothing and wash before reuse

16.7 Training advice

This product is designed for use by professionals.

16.8 Further information

NOTE: The safety analysis of the lyophilized components in this kit has been performed on the reconstituted components. Therefore, the information in this MSDS and product labeling relates to the components as they will be used, i.e. after reconstitution.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported.

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

MSDS established : 2021-10-13

Revision number : 5