

**1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**

1.1	Product name	DIASOURCE IL-1 $\beta$ EASIA kit
	Catalog #	KAP1211
	Kit components	Microtiter plate Calibrators 0 to 5 Specimen diluent Anti-IL-1 $\beta$ -HRP Conjugate Controls 1 and 2 Washing Solution Concentrated Chromogen Substrate Buffer 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: <a href="mailto:tech.support@diasource.be">tech.support@diasource.be</a>
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)****Stop Solution**

Skin irritation 2

**Concentrated Chromogen**

Repro. 1B

Acute toxicity 4

Eye irritation 2

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

Irritation

**Concentrated Chromogen**

Irritation, harmful

**2.1.3 Additional Information**

none

**2.2 Label elements:**

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

**Stop Solution**


H315

P264-P280-P302+352-P321-P332+313-P362

Danger

**Concentrated Chromogen**


H360D-H332-H312-H319

P201-280-P305+351+338-P308+313

Danger

**2.3 Other hazards:**
**Anti-IL-1 $\beta$ -HRP Conjugate**

Contains material from bovine origin

**Calibrators 0 to 5, Controls 1 and 2, Specimen Diluent**

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
<b>Stop Solution containing:</b>		
<b>Sulfuric acid</b>		
CAS-No. 7664-93-9	Skin irritation 2, H315 Xi, R36-38	< 10%
EC-No. 231-639-5		
Index-No. 016-020-00-8		
<b>Concentrated chromogen containing:</b>		
<b>Dimethylformamide</b>		
CAS-No. 68-12-2	Reprod. 1 B, H360D Acute toxicity 4, H332, H312	< 99%
EC-No. 200-679-5		

Index-No. 616-001-00-X	Eye irritation 2,H319	
	T, , Repr.Cat.2, Xn, Xi; R61-20, R21-36	

#### 4. FIRST AID MEASURES

##### 4.1 Description of first aid measures

###### All Kit Components

- After ingestion:*
- Wash out mouth with water provided person is conscious
  - Consult a physician immediately
  - Do not induce vomiting (only applies to Stop Solution)
- After inhalation:*
- Transfer the person to an open place
  - If he does not breathe, proceed to artificial respiration
  - If breathing is difficult, give oxygen
- After skin contact:*
- Wash immediately with plenty of water for at least 15 minutes
  - Remove contaminated clothing and shoes
  - Consult a physician
- After eye contact:*
- Wash immediately with plenty of water for at least 15 minutes
  - Consult a physician

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

No data available.

#### 5. FIRE FIGHTING MEASURES

###### Concentrated Chromogen, 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:*
- Due to small quantities: no special instructions apply

## 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 concentrated chromogen, 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

*Specific purposes:*

- NA

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Components with workplace control parameters

Component	Country		mg/m <sup>3</sup>
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 <sup>3</sup>
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*

- Respiratory Protection* - Use respirators  
*Hand Protection* - Chemical resistant Gloves  
*Eye Protection* - Chemical Safety goggles  
 - Face shields  
*Skin Protection* - Protective Clothing

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

**Microtiter Plate:** plate

**Controls 1 and 2, Specimen Diluent, Calibrators 0 to 5:** Lyophilized, soluble in water

**Washing Solution, Concentrated Chromogen, Stop Solution, Anti-IL-1 $\beta$ -HRP Conjugate, Substrate**

**Buffer:** Liquid

### 9.2 Other Information

No data available

## 10. STABILITY AND REACTIVITY

### Concentrated Chromogen

*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.



## MATERIAL SAFETY DATA SHEET

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

Product name: DIASOURCE IL-1 $\beta$  EASIA kit

Catalog #: KAP1211

*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

#### 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)

May cause congenital malformation in the fetus.

Reproductive toxicity

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

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  $\mu$ g/l

Bioconcentration factor (BCF): < 10

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

No data available

### 12.6 Other adverse effects

**Sulfuric Acid:** Toxic to aquatic life with long lasting effects.

**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, anti-IL-1 $\beta$ -HRP conjugate, Specimen diluent, calibrators 0 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**

T Toxic  
Xn Harmful  
Xi Irritant

**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 R-phrases and/or H-P statements**

R20 Harmful by inhalation.

R21 Harmful in contact with skin

R36/37/38 Irritating to eyes, respiratory system and skin.

R36 Irritating to eyes.

R61 May cause harm to the unborn child

H312 Harmful in contact with skin

H315 Causes skin irritation

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

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

P321 Specific treatment

P332 + P313 If skin irritation 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.

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