

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE IGF-1-ELISA kit
	Catalogue #	KAP1581 – KAR1581
	Kit components	Anti-IGF-1 coated wells HRP Conjugate Conjugate Buffer Pretreatment Solution Reconstitution Solution Neutralization Solution Calibrator 0 Calibrators 1 to 5 Controls 1 and 2 Stop Solution Chromogenic TMB Solution Wash Solution
1.2	Intended Use	In vitro diagnostic use (KAP1581) Research Use Only (KAR1581)
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: tech.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)****Stop Solution**

Skin corrosive 1B

Reconstitution Solution

Flammable liquid cat. 3

Pre-treatment Solution

Flammable liquid cat. 2

Skin corrosive 1B

2.2 Label elements:

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

Stop Solution

H314

P280-P301+330+331-P305+351+338-P309+311

Danger

Reconstitution Solution

H226

P210

Warning

Pre-treatment Solution

H225-H314

P210

P280-P301+330+331-P305+351+338-P309+311

Danger

2.3 Other hazards:**Calibrator 0, Calibrators 1-5, Neutralization Solution, HRP conjugate and Conjugate Buffer**

Contains material from bovine origin.

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.



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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients:

Component	Classification	concentration
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Stop Solution and Pre-treatment Solution containing:

Hydrochloric acid

CAS-No.	7647-01-0	Skin Corrosive CAT 1B, H314	< 5%
EC-No.	231-595-7		
Index-No.	017-002-01-X		

Reconstitution Solution containing:

Ethanol

CAS-No.	64-17-5	Flammable liquid cat. 3, H226	< 10%
EC-No.	200-578-6		
Index-No.	603-002-00-5		

Pre-treatment Solution containing:

Ethanol

CAS-No.	64-17-5	Flammable liquid cat. 2, H225	< 85%
EC-No.	200-578-6		
Index-No.	603-002-00-5		

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 physician.
- After eye contact:*
- Wash immediately with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers.
 - Consult physician.
- After ingestion:*
- Wash out mouth with water provided person is conscious.
 - Do not induce vomiting.
 - Consult immediately a physician
- After inhalation:*
- Transfer the person to an open place.
 - If he does not breathe, proceed to artificial respiration or provide oxygen.
 - If breathing is difficult, give oxygen.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.



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5. FIRE FIGHTING MEASURES

Pretreatment Solution

Suitable extinguishing media:

- Dry chemical powder, water spray, foam, carbon dioxide

Unsuitable extinguishing media:

- No data available

Special exposure hazards:

- Vapor may travel considerable distance to source of ignition and flash back.

- Container explosion may occur under fire conditions.

- Emits toxic fumes under fire conditions.

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.

Other Kit Components

Suitable extinguishing media:

- Powder, water, carbon dioxide, dry sand

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 water

Pretreatment Solution

Personal protection: see 8

Environmental precautions:

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

Clean-up:

- Cover with dry-lime, sand, or soda ash.
- Place in covered containers using non-sparking tools and transport outdoors.
- Ventilate area and wash spill site after material pickup is complete
- Evacuate area
- Shut off all sources of ignition



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7. HANDLING AND STORAGE

Pretreatment Solution

Handling:

- Use non-sparking tools
- Wash thoroughly after handling
- Wash contaminated clothing before reuse.
- Avoid breathing vapor.
- Avoid contact with eyes, skin and clothing.
- Avoid prolonged and repeated exposure
- NIOSH/MSHA-approved respirator
- Compatible chemical-resistant gloves
- Chemical safety goggles

Storage:

- Keep container closed
- Keep away from heat, sparks and open flame
- Store in a cool dry place

Other Kit Components

Handling:

- 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	No. Value	Control parameters	Basis
Hydrochloric acid CAS 7647-01-0	TWA	5 ppm 8 mg/m ³	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
	STEL	10 ppm 15 mg/m ³	
	TWA	1 ppm 2 mg/m ³	UK. EH40 WEL - Workplace Exposure Limits
	STEL	5 ppm 8 mg/m ³	



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Ethanol

Component	Country	Source	Type	Value
Ethanol CAS 64-17-5	Poland		NDS	1900 mg/m3
	Poland		NDSch	-
	Poland		NDSP	-
	Denmark	OEL	TWA	1900 mg/m3
	Germany	TRGS 900	OEL	1900 mg/m3
				11000 ppm
	Norway		OEL	950 mg/m3
				550 ppm
	Sweden		LLV	1000 mg/m3
				500 ppm
	Switzerland	OEL	OEL	960 mg/m3
				500 ppm
	United Kingdom	OEL	OEL	1920 mg/m3
				1000 ppm

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 - Insufficient ventilation: wear respiratory protection

- Government approved respirator (Extraction Solution)

Hand Protection

- Gloves

- Compatible chemical-resistant gloves (Extraction Solution)

Eye Protection

- Safety goggles

- Chemical safety goggles (Extraction Solution)

- Face shields

Skin Protection

- Protective Clothing

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Coated wells: wells

Controls 1 and 2, Calibrator 0, Calibrators 1 to 5: Lyophilized, soluble in water

HRP Conjugate, Conjugate Buffer, Pretreatment Solution, Reconstitution Solution, Neutralization Solution, Chromogenic TMB Solution, Stop Solution, Wash Solution: Liquid

9.2 Other Information

No data available



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10. STABILITY AND REACTIVITY

Pretreatment Solution

Stability : All components are stable until expiry date if stored in specified conditions (see label)

Reactivity/Hazardous decomposition products: Hydrogen chloride gas

Conditions/Materials to avoid: Alkali metals, Ammonia, Oxidizing agents, Peroxides, Bases, Amines, Metals

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: Keep away from metals and acids (Azide containing components)

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

HCl:

Acute toxicity	No data available
Skin corrosion/irritation	Skin - rabbit - Causes burns
Serious eye damage/irritation	Eyes - rabbit - Corrosive to eyes
Respiratory or skin sensitization	No data available.
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	The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.
STOT-repeated exposure	No data available
Aspiration hazard	No data available
Potential Health effects	Inhalation May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract. Causes respiratory tract irritation. Ingestion May be harmful if swallowed. Causes burns Skin May be harmful if absorbed through skin. Causes skin burns. Eyes Causes eye burns.
Signs and Symptoms of Exposure	burning sensation, Cough, wheezing, laryngitis, Shortness of breath, spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonitis, pulmonary edema, Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin.
Additional information	RTECS: MW4025000.

Ethanol:

Acute oral toxicity	LD50 rat: 6.200 mg/kg (IUCLID)
Symptoms: Nausea, Vomiting	
Acute inhalation toxicity	LC50 rat: 95,6 mg/l; 4 h (RTECS)
Absorption symptoms: slight mucosal irritations	
Acute dermal toxicity	This information is not available.
Skin irritation	rabbit Result: No irritation OECD Test Guideline 404 Repeated or prolonged exposure may cause skin irritation and dermatitis, due to degreasing properties of the product.
Eye irritation	This information is not available.
Sensitisation	Sensitisation test (Magnusson and Kligman): Result: negative (IUCLID)
Germ cell mutagenicity	Genotoxicity in vitro Ames test Salmonella typhimurium Result: negative (National Toxicology Program)
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.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity

HCl: Toxicity to fish LC50 - *Gambusia affinis* (Mosquito fish) - 282 mg/l - 96 h

Ethanol: Toxicity to fish LC50 *Leuciscus idus* (Golden orfe): 8.140 mg/l; 48 h (IUCLID)

Toxicity to daphnia and other aquatic invertebrates

EC5 *E.sulcatum*: 65 mg/l; 72 h (Lit.)

EC50 *Daphnia magna* (Water flea): 9.268 - 14.221 mg/l; 48 h (IUCLID)

Toxicity to algae

IC5 *Scenedesmus quadricauda* (Green algae): 5.000 mg/l; 7 d (Lit.)

Toxicity to bacteria

EC5 *Pseudomonas putida*: 6.500 mg/l; 16 h (IUCLID)

12.2 Persistence and degradability

Ethanol: Biodegradability 94 %; OECD Test Guideline 301E. Readily biodegradable.

Biochemical Oxygen Demand (BOD): 930 - 1.670 mg/g (5 d) (Lit.)

Theoretical oxygen demand (ThOD): 2.100 mg/g (Lit.)

Ratio COD/ThBOD: 90 % (Lit.)



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12.3 Bioaccumulative potential

Ethanol: Partition coefficient: n-octanol/water: log Pow: -0,31 (experimental)
(Lit.) Bioaccumulation is not expected.

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

Ethanol : No interference with wastewater treatment plants are to be expected when used properly.
Further information on ecology
Discharge into the environment must be avoided.

13. DISPOSAL CONSIDERATIONS

Provisions relating to waste: Hazardous waste (2008/98/EC). Follow local regulations for radioactive waste.

Packaging/container: Waste material code packaging (2008/98/EC):
15 01 10 (packaging containing residues of or contaminated by dangerous substances)

Disposal methods:

- Patient samples, Calibrator 0, Calibrators 1-5, Neutralization Solution, HRP conjugate, Conjugate Buffer, 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.



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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

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H314 Causes severe skin burns and eye damage

P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

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

P301+330+331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting

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

P309+311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician

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.

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