1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE PTH EASIA kit
	Catalog #	KAP1481
	Kit components	Microtiter plate Calibrator 0 Calibrators 1 to 5 Incubation Buffer Anti-PTH-HRP Conjugate Controls 1 and 2 Washing Solution Chromogenic 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: 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

Incubation Buffer
Aquatic acute cat. 1 – Aquatic chronic cat. 4

2.1.2 Classification according to Directive 1999/45/EC

Stop Solution
Irritation

Incubation Buffer
Dangerous for the environment

2.1.3 Additional Information

none

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

2.3 Other hazards:

Anti-PTH-HRP Conjugate
Contains material from bovine origin
Calibrators 0 to 5
Contains material from 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.
Controls 1 and 2
Contains material from 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
Stop Solution containing:			
Hydrochloric acid			
CAS-No.	7647-01-0	Skin Corrosive CAT 1B, H314	< 5%
EC-No.	231-595-7	Xi	
Index-No.	017-002-01-X		
Incubation Buffer containing:			
Sodium azide			
CAS-No.	26628-22-8	Aquatic Acute 1- Aquatic chronic 4, H413	< 0.01%
EC-No.	247-852-1		
Index-No.	011-004-00-7	T+, N; R28, R50-53	

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

All 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:

- 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	No. Value	Control parameters	Basis
Hydrochloric acid CAS 7647-01-0	TWA	5 ppm 8 mg/m3	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
	STEL	10 ppm 15 mg/m3	
	TWA	1 ppm 2 mg/m3	UK. EH40 WEL - Workplace Exposure Limits
	STEL	5 ppm 8 mg/m3	

Component	No. Value	mg/m^3
Sodium azide CAS 26628-22-8	TLV-TWA	-
	TLV-STEL	-
	TLV-Ceiling	0.29
	OES-LTEL	-
	OES-STEL	0.3
	MAK	0.2
	TRK	
	MAC-TGG 8h	
	MAC-TGG 15min	
	MAC-Ceiling	0.3
	VMA 8h	-
	VMA 15min	0.3
	GWBB 8h	-
	GWBB 15min	-
	Momentary value	0.29
	EC	0.1
	EC-STEL	0.3

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
Eye protection: - Chemical Safety goggles
- Face shield
Hand protection: - Chemical resistant Gloves
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, Calibrator 0, Calibrators 1 to 5: Lyophilized, soluble in water
Washing Solution, Incubation Buffer, Chromogenic TMB, Stop Solution, Anti-PTH-HRP Conjugate: Liquid

9.2 Other Information

No data available

10. STABILITY AND REACTIVITY

All 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

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.

Sodium azide:

Acute oral toxicity	LD50 rat: 27 mg/kg (RTECS)
Absorption symptoms:	Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.
Acute inhalation toxicity	Symptoms: Irritation symptoms in the respiratory tract., Inhalation may lead to the formation of oedemas in the respiratory tract., Symptoms may be delayed.
Acute dermal toxicity	LD50 rabbit: 20 mg/kg (RTECS) (Regulation (EC) No 1272/2008, Annex VI)
Skin irritation	Possible damages: slight irritation
Eye irritation	Possible damages: slight irritation
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.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity

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

Sodium azide: LC50 Lepomis macrochirus (Bluegill sunfish): 0.7 mg/l; 96 h (ECOTOX Database)
EC50 Daphnia pulex (Water flea): 4.2 mg/l; 48 h (ECOTOX Database)
IC50 mixed culture of green algae: 272 mg/l(Lit.)
EC50 Photobacterium phosphoreum: 38.5 mg/l(Lit.)

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Sodium azide: Partition coefficient: n-octanol/water:log Pow: 0.3
OECD Test Guideline 117
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

Sodium azide : Forms toxic mixtures in water, dilution measures notwithstanding.
Herbicide
Nematocidal effect.
Discharge into the environment must be avoided.

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-PTH-HRP conjugate, calibrator 0, calibrators 1 to 5, incubation serum, 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
Xi irritation
T+ Very toxic
N Dangerous for the environment

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

R28 Very toxic if swallowed
R50 Very toxic to aquatic organisms
R53 May cause long term adverse effects in the aquatic environment

H314 Causes severe skin burns and eye damage
H413 May cause long lasting harmful effects to aquatic life

P273 Avoid release to the environment
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
P391 Collect spillage
P501 Dispose of contents/container to …

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.

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