

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	1,25(OH) ₂ Vitamin D ELISA
	Catalog #	KAP1921
	Kit components	Microtiter plate Incubation Buffer Elution Solution Concentrated conjugate Concentrated HRP Conjugate Buffer Calibrators 0 to 5 Controls 1 and 2 Wash Solution Chromogen: TMB Stop Solution Bond Elut Silica Cartridges
1.2	Intended Use	In vitro diagnostic use
1.3	Company	DIASource ImmunoAssays S.A. Rue du Bosquet, 2 B-1348 Louvain-la-Neuve Tel. Nr. +32 (0)10/84.99.11 Belgium 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)*****Incubation Buffer**

Reproductive toxicity (cat 1B), H360D

Conjugate Buffer and Controls

Skin sensitisation CAT 1

Elution Solution

Flammable cat. 2, STOT SE 1, Acute toxicity 3

Stop Solution

Skin corrosive 1B

2.1.2 Classification according to Directive 1999/45/EC**Incubation Buffer, Conjugate Buffer and Controls**

Irritation

Elution Solution

Highly flammable; toxic

2.1.3 Additional Information

none

2.2 Label elements:

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

Incubation BufferH317
P280-P302+352-P333+313-P363

Danger

Conjugate Buffer and ControlsH317
P280-P302+352-P333+313-P363

Danger

Elution SolutionH225-
P210-P233-
P403+235H301+311+331-H370
P280-P302+352-P304+340-P308+310-

Danger

Stop SolutionH314
P280-P301+330+331-P305+351+338-P309+311

Danger

2.3 Other hazards:**Conjugate Buffer**

Contains material from bovine origin.

Calibrators 1 to 5

Contain material from bovine origin.

Controls 1 and 2

Contain 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
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Hazardous ingredients:

Component	Classification	concentration
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Incubation Buffer, Conjugate Buffer and Controls containing:
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	T, N, R43	

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		

Elution Solution containing:
Methanol

CAS-No.	67-56-1	Flam. Liq. 2, Acute Tox. 3, STOT SE1	100%
EC-No.	200-659-6	F; R11 T; R23/24/25-39/23/24/25	
Index-No.	603-001-00-X		

4. FIRST AID MEASURES

4.1 Description of first aid measures
Elution Solution

- 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.

Concentrated HRP and concentrated conjugate

- After skin contact:*
- Wash immediately with soap and plenty of water
- After eye contact:*
- Wash immediately with plenty of water for at least 15 minutes.

4.2 Indication of any immediate medical attention and special treatment needed



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No data available.

5. FIRE FIGHTING MEASURES

Elution Solution

Suitable extinguishing media:

Unsuitable extinguishing media:

Special exposure hazards:

- Dry chemical powder, water spray, foam, carbon dioxide
- No data available
- 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.
- Due to small quantities: no special instructions apply
- Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.

Instructions:

Special protective equipment for firefighters:

Other Kit Components

Suitable extinguishing media:

Unsuitable extinguishing media:

Special exposure hazards:

- All non combustible extinguishing media allowed
- No data available
- No generation of hazardous or toxic gases in dangerous quantities
- Due to small quantities: no special instructions apply
- Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.

Instructions:

Special protective equipment for firefighters:

6. ACCIDENTAL RELEASE MEASURES

Elution 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

Other 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



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Elution 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 Exposure limits

Component	Country	Basis	Type	Value mg/m ³	Value (ppm)	Remarks
Methanol CAS 7647-01-0	Poland		NDS	100	-	-
	Poland		NDSch	300	-	-
	Poland		NDSP	-	-	-
	Denmark	OEL	TWA	260	200	H
	Germany	TRGS 900	OEL	260	200	4, H
	Norway	OEL	TWA	130	100	H
	Sweden		LLV	250	200	H
	Switzerland	OEL	OEL	260	200	H M C
	United Kingdom	OEL	OEL	266	200	Skin Indicative limit value
	United Kingdom	OEL	STEL	333	250	Skin Indicative limit value

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	

8.2 Control of exposure
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
Elution Solution

See 7.

Other Kit Components

Eye protection: - Face shield (Other components)

Hand protection: - Gloves

Suitable materials: - No data available

Skin protection: - Protective clothing

9. PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties



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Microtiter Plate : plate

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

Incubation Buffer, Elution Solution, Concentrated conjugate, Concentrated HRP, Conjugate buffer, Wash Solution, Chromogen(TMB), Stop solution: 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: **Elution Solution:** Heating, Oxidizing substances

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. 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.

HCl:

Acute toxicity	No data available
Skin corrosion/irritation	Skin - rabbit - Causes burns



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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.
Methanol:	
Acute oral toxicity	LDLO human: 143 mg/kg (RTECS) LD50 rat: 5,628 mg/kg (IUCLID) Absorption symptoms: Nausea, Vomiting
Acute inhalation toxicity	LC50 rat: 85.26 mg/l; 4 h (IUCLID) Absorption symptoms: Irritation symptoms in the respiratory tract.
Acute dermal toxicity	LD50 rabbit: ca. 17,100 mg/kg (External MSDS)
Skin irritation	Drying-out effect resulting in rough and chapped skin.
Eye irritation	Irritations of mucous membranes
Sensitisation	Sensitisation test: guinea pig Result: negative (IUCLID)
Germ cell mutagenicity	Genotoxicity in vivo Mutagenicity (mammal cell test): micronucleus. Result: negative (IUCLID)
Genotoxicity in vitro	Ames test Result: negative (IUCLID)
Carcinogenicity	This information is not available.
Reproductive toxicity	This information is not available.
Teratogenicity	This information is not available.
CMR effects	Carcinogenicity: Did not show carcinogenic effects in animal experiments. Mutagenicity: Based on available data the classification criteria are not met. Teratogenicity: Based on available data the classification criteria are not met.



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Specific target organ toxicity (single exposure)	Reproductive toxicity: Based on available data the classification criteria are not met. Target Organs: Eyes Causes damage to organs.
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**Methanol:** Toxicity to fish LC50 – *Lepomis macrochirus* – 15400 mg/l – 96 h**12.2 Persistence and degradability****Methanol:** Biodégradability: 99% 30d**12.3 Bioaccumulative potential****Methanol:** Partition coefficient: n-octanol/water - log Pow: -0.77 (experimental)**12.4 Mobility in soil**

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects**ProClin 300:** An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.**Methanol:** 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:*

- Patient samples, Controls 1 and 2 and Conjugate Buffer 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

N Dangerous for the environment
T Toxic
Xi irritation
F Flammable
STOT SE Specific target organ toxicity - single exposure

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

R11 Highly Flammable
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed
R43 May cause sensitization by skin contact
R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed

H314 Causes severe skin burns and eye damage
H317 May cause an allergic skin reaction
H225 Highly flammable liquid and vapour
H301+311+331 Toxic if swallowed, in contact with skin or if inhaled
H370 Causes damage to organs (Eyes)

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

P233 Keep container tightly closed

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



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P363 Wash contaminated clothing before reuse
P301+330+331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P302+352 IF ON SKIN: Wash with plenty of soap and water
P304+340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
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+310 IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician
P309+311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician
P333+313 If skin irritation or rash occurs: Get medical advice/attention
P403+235 Store in a well-ventilated place. Keep cool.

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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