

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- 1.1 Product name DIASOURCE Rat 25OH Vitamin D total ELISA
- Catalog # KRR1971
- Kit components
Microtiter plate
Incubation Buffer
Concentrated conjugate
Concentrated HRP
Conjugate Buffer
Calibrators 0 to 5
Controls 1 and 2
Wash Solution
Chromogen :TMB
Stop Solution
- 1.2 Intended Use For research use only
- 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)**

Incubation Buffer, Conjugate Buffer, Calibrators 0-5 and Controls
Skin sensitisation CAT 1

Stop Solution
Skin corrosive 1B

2.1.2 Additional Information
none

2.2 Label elements:

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

Incubation Buffer

H317–H360D–H362

P201–P280–P281–P302+352–P308+313–P333+313–P363

Danger

Conjugate Buffer, Calibrators 0-5 and Controls

H317

P280–P302+352–P333+313–P363

Danger

Stop Solution

H314

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

Danger

2.3 Other hazards:**Incubation Buffer**

Contains proteins from bovine, ovine and murine origin

Conjugate Buffer

Contains proteins from bovine origin.

Calibrators 0 to 5

Contain material from equine origin.

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.

Controls 1 and 2

Contain material from murine origin.

3. COMPOSITION/INFORMATION ON INGREDIENTS
Hazardous ingredients:

Component	Classification	concentration
Incubation Buffer 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 T, N, R43	< 0,06%
Index-No. 613-167-00-5		
Penta deca fluoro octanoic acid - PFOA		
CAS-No. 335-67-1	Acute toxicity, Oral CAT 4, H302 C, R22-34-52/53	< 3%
EC-No. 206-397-9		

Calibrators 0-5, Controls and Conjugate Buffer 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 T, N, R43	< 0,06%
Index-No. 613-167-00-5		

Stop Solution containing:

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

4. FIRST AID MEASURES
4.1 Description of first aid measures
Stop Solution, Incubation Buffer, Conjugate Buffer, Calibrators 0-5 and Conjugate

After skin contact: - Wash immediately with soap and plenty of water for at least 10 minutes.

- Consult a physician.

- Remove and wash contaminated clothing before re-use.

After eye contact: - 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.

4.2 Indication of any immediate medical attention and special treatment needed

No data available.



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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:

- 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:

- 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



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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	

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

Hand Protection - Gloves

Eye Protection - 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, Calibrators 0 to 5 : Lyophilized, soluble in water

Washing Solution, concentrated conjugate, concentrated HRP, Incubation Buffer, Conjugate buffer, Stop solution, Chromogen(TMB) : 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



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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
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.



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Signs and Symptoms of Exposure	Eyes	Causes eye burns.
		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.
PFOA:		
Acute toxicity		LD50 Intraperitoneal - rat - 189 mg/kg
Skin corrosion/irritation		No data available
Serious eye damage/irritation		No data available
Respiratory or skin sensitization		No data available.
Germ cell mutagenicity		Genotoxicity in vivo - rat – Oral: DNA damage Genotoxicity in vivo - rat – Intraperitoneal: DNA damage
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	May be 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.
Signs and Symptoms of Exposure		Cough, Shortness of breath, Headache, Nausea, Vomiting
Additional information		RTECS: RH0781000.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity

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

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available



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12.6 Other adverse effects

ProClin 300: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

PFOA: Harmful to aquatic life.

13. DISPOSAL CONSIDERATIONS

Provisions relating to waste: Hazardous waste must be treated according to local regulations

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

Disposal methods:

- Patient samples, Calibrators 0 to 5 ,Controls 1 and 2 , incubation buffer 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

16.3 Key literature references and sources for data
SDS sheets provided by suppliers of raw materials.



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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

H314 Causes severe skin burns and eye damage

H317 May cause an allergic skin reaction

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

P301+330+331 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

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

P363 Wash contaminated clothing 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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