

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product: Angiotensin I (PRA)-RIA
Catalog #: KIP5361
Kit Components: Coated Tubes
Tracer
Calibrators 0-5
Dilution Buffer
Wash Solution
Controls
Enzymatic Inhibitor

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 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) no 1272/2008 (CLP)

Dilution Buffer, Calibrators 0-5, Controls, Tracer

Skin sensitisation cat. 1.

Enzymatic Inhibitor

Flammable liquid cat. 2

2.1.2 Additional Information

Classification according to radioprotection regulations.


Tracer

Contains radioactive material.


2.2 Label elements

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

Dilution Buffer, Calibrators 0-5, Controls, Tracer

	H317
	P280–P302+352–P333+313-P363
Danger	

Enzymatic Inhibitor

	H225
	P210 – P233 – P240 – P403+235
Danger	

2.2.2 Labeling according to radioprotection regulations

Tracer



2.2.3 Other labeling

Tube : each tube can only be used once



2.3 Other hazards

Tracer

Contains material from bovine origin
 150 kBq

Coated Tubes

Contains material from bovine origin

Calibrators 0-5

Contains material from bovine origin

Controls

Contains material from bovine origin

3 COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients:

Component	Classification	concentration
-----------	----------------	---------------

Dilution Buffer, Calibrators 0-5, Controls, Tracer 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		

Enzymatic Inhibitor containing:

Ethanol

CAS-No.	64-17-5	Flammable liquid cat. 2, H225	< 98 %
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 a physician in case of inflammation.
 - In the case of a wound or cut rinse with plenty of water, then dress the wound.
- After eye contact:*
- Wash immediately with plenty of water for at least 15 minutes.
 - Consult immediately a physician
- After ingestion:*
- Let drink a lot of water.
 - Consult immediately a physician if ingested in large quantities
- 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.

5 FIRE FIGHTING MEASURES

- 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

Personal protection: see 8

Environmental precautions:

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

Clean-up:

- The radioactive material should be wiped up immediately
- 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

7.1 Handling

- Handle radioactive material according to radioprotection rules
- Observe normal hygiene standards
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

7.2 Storage

- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, combustible materials, acids, metals
- Storage temperature: see component label

7.3 Specific Use(s)

- NA

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Component	Country	Source	Type	Value
Ethanol CAS 64-17-5	Poland		NDS	1900 mg/m ³
	Poland		NDSch	-
	Poland		NDSP	-
	Denmark	OEL	TWA	1900 mg/m ³
	Germany	TRGS 900	OEL	1900 mg/m ³
				11000 ppm
	Norway		OEL	950 mg/m ³
				550 ppm
	Sweden		LLV	1000 mg/m ³

				500 ppm
	Switzerland	OEL	OEL	960 mg/m ³
				500 ppm
	United Kingdom	OEL	OEL	1920 mg/m ³
				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

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

I¹²⁵

Half-life: 59.9 days

Specific activity: 6.4 x 10¹⁴ Bq.g⁻¹

Coated Tubes: Tubes

Other components : liquid

9.2 Other Information

No data available.

10 STABILITY AND REACTIVITY

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

11 TOXICOLOGICAL INFORMATION

I¹²⁵ labeled component(s):

Chronic and acute effects

Radioactivity related adverse effects are only observed at exposure levels that are very much higher than those experienced with the reagents in this kit.

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.

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 Aquatic toxicity

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 Mobility in soil

No data available.

12.3 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.)

12.4 Bioaccumulative potential

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

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

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

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 (91/689/EEC). Follow local regulations for radioactive waste.

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:

- Radioactive material should be disposed of following local regulations regarding radioactive waste.
- Patient samples, tracer, Calibrators, Controls 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

According to ADR and IATA (Chapter 10.3.1) regulations , shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods. If the shipment exceed this quantity, please refer to the information given below:

Radioactive material, N.O.S., UN 2910 - except package

Land transport	AIEA/ADR/RID regulation (Class 7, fiche 1 - ADR)
Sea transport	IMDG regulation
Air transport	OACI/IATA regulation

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

16.2 Abbreviations and acronyms

None

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

H225 Highly flammable liquid and vapour
H317 May cause an allergic skin reaction.

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

P233: Keep container tightly closed.

P240: Ground/bond container and receiving equipment.

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

P302+352 IF ON SKIN: Wash with plenty of soap and water.

P333+313 If skin irritation or rash occurs: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

P403+235: Store in a well ventilated place. Keep cool.

16.6 Training advice

This product is designed for use by professionals.

16.7 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.



MATERIEL SAFETY DATA SHEET

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

Product Name: Angiotensin I (PRA)-RIA

Catalog #: KIP5361

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.

16.8 Notification:

English is acceptable for our MSDS as the following conditions are met:

- Medical specialists (users) are well educated in the English language

MSDS established : 2019-10-30

Revision number : 2