1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE SM-C-RIA-CT kit
	Catalog #	KIP1589
	Kit components	Anti-SM-C Coated tubes ^{125}I-SM-C Standard 0 Standards 1 to 5 Reconstitution Solution Pretreatment Solution Neutralisation Solution Controls 1, 2 and 3 Washing 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)

Reconstitution Solution
Flammable liquid cat. 3

Pre-treatment Solution
Flammable liquid cat. 2
Skin corrosive 1B

^{125}I-SM-C, Neutralisation Solution, Standards
Aquatic acute cat. 1 – Aquatic chronic cat. 4

2.1.2 Classification according to Directive 1999/45/EC

Pre-treatment and Reconstitution Solution
Flammable liquid

^{125}I-SM-C, Neutralisation Solution, Standards
Dangerous for the environment

2.1.3 Additional Information

Classification according to radioprotection regulations.

^{125}I-SM-C
Contains radioactive material

2.2 Label elements:

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

Reconstitution Solution

H226
P210

Warning

Pretreatment Solution

H225-H314
P210
P280-P301+330+331-P305+351+338-P309+311

Danger

2.2.2 Labeling according to radioprotection regulations

^{125}I-SM-C

2.3 Other hazards:

^{125}I-SM-C	Contains material from bovine origin
	Tracer: 130 kBq
Standard 0	Contains ovalbumin
Standards 1 to 5	Contains ovalbumin
Controls 1, 2 and 3	Contains material from human origin

Although these human 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
Pretreatment 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		
Ethanol			
CAS-No.	64-17-5	Flammable liquid cat. 2, H225	< 85%
EC-No.	200-578-6	F, R11	
Index-No.	603-002-00-5		
Reconstitution Solution containing:			
Ethanol			
CAS-No.	64-17-5	Flammable liquid cat. 3, H226	< 15%
EC-No.	200-578-6	F, R10	
Index-No.	603-002-00-5		
^{125}I-SM-C, Neutralisation Solution, Standards containing:			
Sodium azide			
CAS-No.	26628-22-8	Aquatic Acute 1- Aquatic chronic 4, H413	< 0.05%
EC-No.	247-852-1	T+, N; R28, R50-53	
Index-No.	011-004-00-7		

4. FIRST AID MEASURES

4.1 Description of first aid measures

Pretreatment 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.

All Other 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.
- Remove contaminated clothing

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 or if any complaints

After inhalation:
- Transfer the person to an open place.
- If he does not breathe, proceed to artificial respiration or provide oxygen.
- Consult a physician.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

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.

All Kit Other 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

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

All Other Kit Components
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

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

All Other Kit Components
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

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	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

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

Pretreatment Solution
See 7.

All Other Kit Components
Eye protection: - Safety goggles (^{125}I-SM-C)
- Face shield (Other components)
Hand protection: - Gloves
Suitable materials: - No data available
Skin protection: - Protective clothing

Operators handling radioactive material should be monitored according to local regulations regarding occupational medicine.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

I^{125}
Half-life : 59.9 days
Specific activity : 6.4 x 10^{14} $Bq.g^{-1}$

Coated Tubes: Tubes
Controls 1, 2 and 3, Standards 0, Standards 1 to 5 : Lyophilized
Other components : Liquid

9.2 Other Information

No data available

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.

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

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)

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

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.)

12.3 Bioaccumulative potential

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

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

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.

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). 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, ^{125}I-SM-C, Standard 0, Standards 1 to 5, Controls 1, 2 and 3 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.
- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides.

14. TRANSPORT INFORMATION

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
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
F flammable
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

R10 Flammable
R11 Highly flammable
R28 Very toxic if swallowed
R50 Very toxic to aquatic organisms
R53 May cause long term adverse effects in the aquatic environment

H225 Highly flammable liquid and vapour.
H226 Flammable liquid and vapour.
H314 Causes severe skin burns and eye damage
H413 May cause long lasting harmful effects to aquatic life

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

This MSDS assumes that radioprotection principles and applicable regulations are known by the user.

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.

MSDS established : 2015-05-08
Revision number : 2