

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- | | | |
|-----|----------------|---|
| 1.1 | Product name | DIASOURCE CA 19-9-IRMA kit |
| | Catalog # | KIP0311 |
| | Kit components | Avidine Coated tubes
¹²⁵ I-anti-CA 19-9 (monoclonal Abs)
Calibrators 0 to 5
Biotin Anti CA 19-9 (monoclonal Abs)
Controls 1 and 2
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)**

¹²⁵I-anti-CA 19-9 (monoclonal Abs) and Calibrators 0
Aquatic acute cat. 1 – Aquatic chronic cat. 4

2.1.2 Classification according to Directive 1999/45/EC

¹²⁵I-anti-CA 19-9 (monoclonal Abs) and Calibrators 0
Dangerous for the environment

2.1.3 Additional Information

Classification according to radioprotection regulations.

¹²⁵I-anti-CA 19-9 (monoclonal Abs)
Contains radioactive material

2.2 Label elements:

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


No label required

2.2.2 Labeling according to radioprotection regulations

¹²⁵I-anti-CA 19-9 (monoclonal Abs)



2.2.3 Other labeling

Tube : each tube can only be used once 

2.3 Other hazards:

¹²⁵ I-anti-CA 19-9	Contains material from bovine origin Tracer: 380 kBq
Calibrators 0 to 5	Contains material from bovine origin
Biotin Conjugate	Contains material from bovine origin
Controls 1 and 2	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
¹²⁵ I-anti-CA 19-9 (monoclonal Abs) and Calibrators 0 containing:		
Sodium azide		
CAS-No.	26628-22-8	Aquatic Acute 1- Aquatic chronic 4, H413 T+, N; R28, R50-53
EC-No.	247-852-1	
Index-No.	011-004-00-7	
		< 0.1%



MATERIAL SAFETY DATA SHEET

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

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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.
- After eye contact:*
- In the case of a wound or cut rinse with plenty of water, then dress the wound.
 - 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.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE FIGHTING MEASURES

All Kit 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

All 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 water
- Wash clothing according to radioprotection rules



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7. HANDLING AND STORAGE

All 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

Specific purposes:

- NA

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

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.



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8.2.2 Personal protection equipment

All Kit Components

Respiratory Protection - Insufficient ventilation: wear respiratory protection

Hand Protection - Gloves

Eye Protection - Safety goggles (¹²⁵I-anti-CA 19-9)

- Face shields

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

I¹²⁵

Half-life : 59.9 days

Specific activity : 6.4×10^{14} Bq.g⁻¹

Coated Tubes: Tubes

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

Calibrator 0, Washing Solution, ¹²⁵I-anti-CA 19-9, Biotin 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: Keep away from metals and acids (Azide containing components)

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

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.

Sodium azide:

Acute oral toxicity

LD50 rat: 27 mg/kg (RTECS)

Absorption symptoms:

Irritations of mucous membranes in the mouth, pharynx, oesophagus



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Acute inhalation toxicity	and gastrointestinal tract. 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

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.



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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, ¹²⁵I-anti-CA 19-9, Calibrators 0 to 5, Biotin Anti CA 19-9, 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.
- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides.

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

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

T+ Very toxic

N Dangerous for the environment



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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

H413 May cause long lasting harmful effects to aquatic life

P273 Avoid release to the environment

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.



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16.9 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 : 2019-11-22

Revision number : 3