

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Tg-S-IRMA
 Catalog #: R-CM-100
 Kit Components: ¹²⁵I- Tracer
 Calibrators
 Control
 Tubes
 Washing Solution
 Recovery Solution
 Diluent Buffer

1.2 Intended Use

For in vitro diagnostic 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 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

Component	Hazardous ingredients
Coated Tubes	-
Tracer	contains sodium azide (< 0.1 % w/w) radioactivity < 480 kBq
Calibrator zero	contains sodium azide (< 0.1 % w/w)
Calibrators	contains sodium azide (< 0.1 % w/w)
Control	contains sodium azide (< 0.1 % w/w)
Washing Solution	contains sodium azide (< 0.1 % w/w)
Recovery Solution	contains sodium azide (< 0.1 % w/w)
Diluent Buffer	contains sodium azide (< 0.1 % w/w)

Labeling:

Tube : each tube can only be used once



3 COMPOSITION/INFORMATION ON INGREDIENTS

Tracer: exposition to ionising radiation without protection may undergo external exposure or irradiation and internal exposure through ingestion, contact with skin or inhalation.

All components : sodium azide can react with lead and copper pipes to form highly explosive metal azides. When disposing of the product, rinse abundantly with water. At concentrations below 0.1 % by weight sodium azide does not present any danger.

4 FIRST AID MEASURES

As a general rule, if an accident involving inhalation, skin contact, ingestion, or a cut occurs, consult a hospital emergency medical department immediately and show it this sheet.

Never try to get an unconscious person to swallow anything. If the person is unconscious, place her/him on her/his side in the standard safety position and wait for medical assistance.

If breathing is irregular or stops, perform artificial respiration while waiting for medical assistance to arrive.

Tracer

Contact with skin : immediately remove the contaminated clothing without contaminating other parts of the body. Wash the skin with sudsy soap and water and rinse with plenty of water. Check for the absence of radioactive contamination using a dosimeter. If traces of contamination are detected, wash again. Avoid irritating the skin so as to prevent damaging it, which will facilitate the radioelement's entry into the body. In the case of a wound or cut, rinse abundantly with water, then dress the wound. Consult a hospital emergency medical department without delay.

Contact with eyes : rinse immediately with water, keeping the eyelids wide open at least 15 minutes. Check for the absence of radioactive contamination using a dosimeter. Consult a hospital emergency medical department immediately.

Ingestion : let drink water. Consult a hospital emergency medical department immediately if ingested large quantities.

Inhalation : transfer to an open place and consult a hospital emergency medical department.

5 FIRE FIGHTING MEASURES

Extinguishing compounds : powder, water, CO₂

Specific hazards : none

Protection of fire-fighters : Wear a breathing apparatus and protective clothing. Avoid contact with the skin and eyes.

6 ACCIDENTAL RELEASE MEASURES

Individual precautions : see 8.

Environmental precautions : do not pour contaminated materials down the drain, but dispose of them in a rubbish bin for radioactive waste or in a rubbish bin for material of human origin. All wastes must be disposed of in conformity with the local regulations.

Cleaning methods :Tracer

Splashes on clothing : take off the contaminated clothing as quickly as possible and place it in a rubbish bin for discarding radioactive waste. Check that there is no contamination of the skin.

Spills on equipment : soak up the liquid with some disposable absorbent material, making sure not to spread the area of contamination.

7 HANDLING AND STORAGE

Handling : handle the reagents of human origin as if they were potentially infectious. Wear disposable gloves, properly closed protective clothing, and protective goggles. Avoid all contact with the skin and eyes. Wash hands after handling all materials. Do not drink, eat, smoke, or apply make-up. Do no pipette with the mouth. Consult the instructions for use.

Storage : close the reagent's containers well so that they are airtight. Observe the storage conditions mentioned on the labels. The shelf-life date and batch number are printed on the packaging. Keep the reagents in their original packaging and shipping containers until use.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Technical measures : -

Individual protective equipment : goggles, disposable gloves, protective clothing, face shield.

9 PHYSICAL AND CHEMICAL PROPERTIES

Coated Tubes : plastic tubes

Tracer : red liquid, emission of gamma rays, radioactive half-life: 60 days

Washing Solution : colourless liquid

Calibrator zero, Calibrators, Control, Recovery Solution : orange liquid

Diluent Buffer : colourless liquid

10 STABILITY AND REACTIVITY

Stability : under normal conditions of storage and use the reagents are stable up to the shelf-life date indicated on the labels. All reagents must be stored in specified conditions (see label).

Dangerous reactions : sodium azide can react with metals to form highly explosive metal azides.

Materials to avoid : metals.

Dangerous decomposition products : none

11 TOXICOLOGICAL INFORMATION

Tracer : anyone who is exposed to ionising radiation without protection may undergo : external exposure or irradiation and internal exposure through ingestion, contact with the skin, or inhalation. Due to small quantities of radioactivity, no chronic or acute adverse effects have to be feared.

Other components : no known chronic effects.

12 ECOLOGICAL INFORMATION

All reactivities must be disposed of in conformity with existing local legislation. Due to small quantities of reactivities, no effects have to be feared.

13 DISPOSAL CONSIDERATIONS

Waste residues : human origin wastes must be disposed of in conformity with existing local legislation.

Soiled packaging : dispose of in accordance with existing legislation. Contaminated containers must be treated the same way as the respective chemicals. Waste material packaging code (2001/118/EC) : 15 01 10 (packaging containing or contaminated by dangerous substances).

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., UN2910 – except package

Road transport : AIEA/ADR/RID regulation (Class 7, fiche 1 – ADR)

sea transport : IMDG regulation

Air transport : AOCI/IATA regulation

15 REGULATORY INFORMATION

CLP regulation

REACH regulation

Radioprotection regulations.

Labelling : Tracer



16 OTHER INFORMATION

Intended use : for in vitro diagnostic use only. For professional use only.

Radioprotection : radioprotection principles and applicable regulations are known by the user.

Notification:

English is acceptable for our documents open to the users as the following conditions are met:

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

This information sheet completes but does not replace the technical instructions for use. The information that it contains is based on the state of knowledge about the product concerned on the day it was updated. This information is given in good faith.

We also draw the user's attention to the risks that may be run when a product is used for uses other than the ones for which it was designed.

In no event does this information sheet dispense the user from knowing and applying all of the legislation that regulates his activity. The sole aim of all of the regulatory stipulations mentioned herein is to help the recipient to satisfy the obligations incumbent upon him when a dangerous product is used.

This list must not be considered exhaustive. It does not exonerate the user from ensuring that he need not meet other obligations pursuant to texts other than those mentioned herein that govern the possession and use of the product, for which he alone is liable.

MSDS established : 2020-03-24

Revision number : 2