

MATERIAL SAFETY DATA SHEET

In compliance with 2006/1907/EG

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

PRODUCT NAME: TPAcyk™ IRMA


CATALOGUE NUMBER: 10-021

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2. HAZARDS IDENTIFICATION

TPAcyk™ IRMA ¹²⁵I Tracer contains radioactive material, see radioprotection regulation. None of other hazardous reagents are present in amount that qualifies the products as hazardous according to directive 67/548/EC and 1272/2008/EC.

Component number	Component Name	Hazard	Applicable Risk (R) and Safety (S) phrases according to EC directives
1	TPAcyk™ IRMA Coated Beads	NA	NA
2	TPAcyk™ IRMA ¹²⁵ I Tracer	Radioactive material exposure can cause cancer and reproductive harm. Material of animal origin: should be considered as potentially infectious	
3	TPAcyk™ IRMA Diluent (Standard 0 U/l)	Splashes on skin, eyes and ingestion may cause irritation. Material of animal origin: should be considered as potentially infectious	NA
4	TPAcyk™ IRMA Standard 0.5 ng/ml Standard 1 ng/ml Standard 2 ng/ml Standard 5 ng/ml Standard 15 ng/ml Standard 30 ng/ml	Splashes on skin, eyes and ingestion may cause irritation. Material of animal origin: should be considered as potentially infectious	NA
5	TPAcyk™ IRMA Control Low Control High	Splashes on skin, eyes and ingestion may cause irritation. Material of animal origin: should be considered as potentially infectious	NA
6	Wash Tablet	NA	NA

3. COMPOSITION/INFORMATION ON INGREDIENTS

The kit contains the following components: TPAcyk™ IRMA Coated Beads, ¹²⁵I Tracer, Sample Diluent, Standards and Kit Controls, Wash Tablet.

TPAcyk™ IRMA ¹²⁵I Tracer contains radioactive material that emits ionizing radiation, γ-ray (35 keV), Kα X-ray (28 keV) and Kβ X-ray (31 keV). Half-life 60 days. See 67/548/ECC, 1272/2008/EC and radioprotection regulation.

No other single component contains a hazardous ingredient in an amount that requires labeling. Hazardous ingredients are given below:

	Component Name	Ingredient	Concentration	CAS#	EC#	Classification (pure ingredient)	Classification (kit component)
2	TPAcyk™ IRMA ¹²⁵ I Tracer	Iodine-125	Radioactivity < 1.1 MBq/vial (< 1.1 MBq/kit)	14158-31-7	-	Radioactive material Xn, N, R20/21, R50	Radioactive material
2	TPAcyk™ IRMA ¹²⁵ I Tracer	ProClin 300	≤ 0.2 %	55965-84-9	247-500-7/ 220-239-6	T, N; R23/24/25, R34, R43, R50/53	NA
3	TPAcyk™ IRMA Diluent (Standard 0 U/l)						
4	TPAcyk™ IRMA Standard (0.5, 1, 2, 5, 15, 30 ng/ml)						
5	TPAcyk™ IRMA Control High/Low						
2	TPAcyk™ IRMA ¹²⁵ I Tracer						
3	TPAcyk™ IRMA Diluent (Standard 0 U/l)	Animal originating protein stabilizers	< 10 %	-	-	NA	NA
4	TPAcyk™ IRMA Standard (0.5, 1, 2, 5, 15, 30 ng/ml)						
5	TPAcyk™ IRMA Control High/Low						

4. FIRST AID MEASURES

- Inhalation:** Remove person to fresh air. If needed, get medical attention.
- Eye contact:** Immediately flush eyes with plenty of water for at least 15 minutes, remove contact lenses if any. Seek medical advice.
- Skin contact:** Remove contaminated clothing. Wash well with mild soap and plenty of water. If skin is broken or material gets into open wound, seek medical advice.
- Ingestion:** Flush mouth with plenty of water (do not swallow). Drink large amounts of water. Seek medical advice.

5. FIRE-FIGHTING MEASURES

- Suitable extinguish media:** Powder, water, carbon dioxide or dry sand.
- Special exposure hazards:** No generation of hazardous or toxic gases in dangerous quantities.
- Protective equipment:** Self-contained breathing apparatus and protective clothing to avoid all contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions:** See section 8.
- Environmental precautions:** Prevent soil and water pollution. Dispose of according section 13.
- Clean up:** Absorb spills with absorbent material, use personal protection of according to section 8, dispose of according to section 13.

7. HANDLING AND STORAGE

- Handling:** Handle radioactive material according to local regulations
Do not eat, drink, smoke or apply cosmetics.
- Storage:** Store in well closed original container at 2-8°C. Do not freeze.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Eye protection:** Safety goggles
- Hand protection:** Disposable gloves
- Skin protection:** Laboratory coat
Half-value layer for lead shielding is 0.02 mm

9. PHYSICAL AND CHEMICAL PROPERTIES

Component number	1	2	3	4	5	6
Physical state	Solid (Beads)	Liquid	Liquid	Liquid	Solid (Lyophilized)	Solid (Tablet)
Color	White	Red	Colourless	Colourless	Yellow	White
Odor	Odorless	Odorless	Odorless	Odorless	Odorless	Odorless
pH	NA	7.5	7.5	7.5	7.5	7.4
Solubility in water	NA	Miscible	Miscible	Miscible	Miscible	Miscible

10. STABILITY AND REACTIVITY

Stability: Until expiry date stated on label if stored under specified conditions.

Reactivity/Hazardous decomposition products: None.

Conditions/materials to avoid: None.

11. TOXICOLOGICAL INFORMATION

TPAcyk™ IRMA ¹²⁵I Tracer

Irritant: Splashes on skin, eyes and ingestion may cause irritation.

Acute toxic: No data available

Carcinogenicity: Radioactivity can cause cancer

Germ cell mutagenicity: No data available

Reproductive toxicity: Radioactivity can cause reproductive harm

Other kit components

Irritant: Splashes on skin, eyes and ingestion may cause irritation.

Acute toxic: 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.

Germ cell mutagenicity: No data available

Reproductive toxicity: No data available

12. ECOLOGICAL INFORMATION

Toxicity: Toxic to fish and other water organisms.

Persistence and degradability: No data available

Bioaccumulative potential: No data available

Mobility in soil: No data available

PBT and vPvB assessment: No data available

Other adverse effects: No data available

13. DISPOSAL CONSIDERATIONS

All kit components and tested specimen should be considered as biohazard/infectious and radioactive waste and should be disposed of in accordance with federal, state and local environmental regulations.

14. TRANSPORT INFORMATION

Typ of product	Laboratory reagents
Class:	UN 2910
Transport:	Transported at 2-8°C

15. REGULATORY INFORMATION AND CONSIDERATIONS

Classification according to directives 67/548/ECC, 1272/2008/EC and radioprotection regulation.

TPAcyk™ IRMA ¹²⁵I Tracer

 RADIOACTIVE MATERIAL

No other single component contains a hazardous ingredient in an amount that requires identification and labeling.

16. OTHER INFORMATION

This product is designed for use by professionals and for in vitro diagnostics use only.
This MSDS presumes that basic rules for radioprotection and applicable regulations are known by the user.
All material from animal origin has been collected from healthy animals.
Bovine components originate from countries where BSE has not been reported.

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