

## MATERIAL SAFETY DATA SHEET

*In compliance with 2006/1907/EG*

### 1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

**PRODUCT NAME:** MonoTotal® IRMA


**CATALOGUE NUMBER:** 10-028

**MANUFACTURER:** IDL Biotech [www.idl.se](http://www.idl.se)  
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### 2. HAZARDS IDENTIFICATION

MonoTotal® IRMA <sup>125</sup>I 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                | MonoTotal® IRMA Coated Beads   | NA   | NA  |
| 2                | MonoTotal® IRMA <sup>125</sup> I Tracer  | Radioactive material exposure can cause cancer and reproductive harm.<br><br>Material of animal origin: should be considered as potentially infectious |  |
| 3                | MonoTotal® IRMA Diluent (Standard 0 U/l)   | Splashes on skin, eyes and ingestion may cause irritation.<br><br>Material of animal origin: should be considered as potentially infectious            | NA  |
| 4                | MonoTotal® IRMA<br>Standard 50 U/l<br>Standard 100 U/l<br>Standard 500 U/l<br>Standard 2000 U/l<br>Standard 6000 U/l | Splashes on skin, eyes and ingestion may cause irritation.<br><br>Material of animal origin: should be considered as potentially infectious            | NA  |
| 5                | MonoTotal® IRMA<br>Control Low<br>Control High   | Splashes on skin, eyes and ingestion may cause irritation.<br><br>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: MonoTotal® IRMA Coated Beads, <sup>125</sup>I Tracer, Sample Diluent, Standards and Kit Controls, Wash Tablet.

MonoTotal® IRMA <sup>125</sup>I 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 | MonoTotal® IRMA <sup>125</sup> I Tracer                 | Iodine-125                             | Radioactivity<br>< 1.1 MBq/vial<br>(< 1.1 MBq/kit) | 14158-31-7 | -                       | Radioactive material<br>Xn, N, R20/21, R50 | Radioactive material           |
| 2 | MonoTotal® IRMA <sup>125</sup> I Tracer                 | ProClin 300                            | ≤ 0.2 %  | 55965-84-9 | 247-500-7/<br>220-239-6 | T, N, R23/24/25,<br>R34, R43, R50/53       | NA                             |
| 3 | MonoTotal® IRMA Diluent (Standard 0 U/I)                |  |  |            |                         |  |                                |
| 4 | MonoTotal® IRMA Standard (50, 100, 500, 2000, 6000 U/I) |  |  |            |                         |  |                                |
| 5 | MonoTotal® IRMA Control High/Low                        |  |  |            |                         |  |                                |
| 2 | MonoTotal® IRMA <sup>125</sup> I Tracer                 | Animal originating protein stabilizers | < 10 %   | -          | -                       | NA   | NA                             |
| 3 | MonoTotal® IRMA Diluent (Standard 0 U/I)                |  |  |            |                         |  |                                |
| 4 | MonoTotal® IRMA Standard (50, 100, 500, 2000, 6000 U/I) |  |  |            |                         |  |                                |
| 5 | MonoTotal® 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

### MonoTotal® IRMA <sup>125</sup>I 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**

|                        |                      |
|------------------------|----------------------|
| <b>Type of product</b> | Laboratory reagents  |
| <b>Class:</b>          | UN 2910              |
| <b>Transport:</b>      | Transported at 2-8°C |

**15. REGULATORY INFORMATION AND CONSIDERATIONS**

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

MonoTotal® IRMA <sup>125</sup>I 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.

THE INFORMATION PROVIDED IN THIS MSDS IS CORRECT TO THE BEST OF OUR KNOWLEDGE, INFORMATION AND BELIEF AT THE DATE OF ITS PUBLICATION. THE USER SHOULD DETERMINE THE SUITABILITY OF THIS INFORMATION FOR THE INTENDED USE OF THE PRODUCT AND ADOPT APPROPRIATE SAFETY PRECAUTIONS. IDL BIOTECH AB SHALL NOT BE LIABLE OR OTHERWISE RESPONSIBLE IN ANY WAY FOR ANY DAMAGE RESULTING FROM HANDLING OR FROM CONTACT WITH THE ABOVE PRODUCT. THE USER IS ALSO RESPONSIBLE FOR OBSERVING ANY LAWS AND APPLICABLE GUIDELINES.

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