

# **MATERIAL SAFETY DATA SHEET**

In compliance with 2006/1907/EG

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

PRODUCT NAME: UBC<sup>®</sup> IRMA

CATALOGUE NUMBER: 10-022

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# 2. HAZARDS IDENTIFICATION

UBC<sup>®</sup> 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	UBC <sup>®</sup> IRMA Coated Beads	NA	NA
2	UBC <sup>®</sup> IRMA <sup>129</sup> I Tracer	Radioactive material exposure can cause cancer and reproductive harm. Material of animal origin: should be considered as potentially infectious	*
3	UBC <sup>®</sup> IRMA Urine Diluent	Splashes on skin, eyes and ingestion may cause irritation. Material of animal origin: should be considered as potentially infectious	NA
4	UBC <sup>®</sup> IRMA Diluent (Standard 0 µg/l)	Splashes on skin, eyes and ingestion may cause irritation. Material of animal origin: should be considered as potentially infectious	NA
5	UBC <sup>®</sup> IRMA Standard 1 µg/l Standard 2 µg/l Standard 5 µg/l Standard 15µg/l Standard 15µg/l Standard 30 µg/l	Splashes on skin, eyes and ingestion may cause irritation. Material of animal origin: should be considered as potentially infectious	NA
6	UBC <sup>®</sup> 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
7	Wash Tablet	NA	NA



## 3. COMPOSITION/INFORMATION ON INGREDIENTS

The kit contains the following components: UBC<sup>®</sup> IRMA Coated Beads, <sup>125</sup>I Tracer, Sample Diluent, Standards and Kit Controls, Wash Tablet.

UBC<sup>®</sup> IRMA <sup>125</sup>I Tracer contains radioactive material that emits ionizing radiation,  $\gamma$ -ray (35 keV), K $\alpha$  X-ray (28 keV). and K $\beta$  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	UBC <sup>®</sup> IRMA <sup>128</sup> I Tracer		lodine-125	Radioactivity < 1.1 MBq/vial (< 1.1 MBq/kit)	14158-31-7	-	Radioactive material Xn, N, R20/21, R50	Radioactive material
2 3 4 5 6	<ol> <li>UBC<sup>®</sup> IRMA Urine Diluent</li> <li>UBC<sup>®</sup> IRMA Diluent (Standard 0 μ/l)</li> <li>UBC<sup>®</sup> IRMA Standard (1, 2, 5, 15, 30 μg/l)</li> </ol>		ProClin 300	≤ 0.5 %	55965-84-9	247-500-7/ 220-239-6	T,N; R23/24/25, R34, R43, R50/53	NA
2 3 4 5 6	<ul> <li>3 UBC<sup>®</sup> IRMA Urine Diluent</li> <li>4 UBC<sup>®</sup> IRMA Diluent (Standard 0 μ/I)</li> </ul>		Animal originating protein stabilizers	< 10 %	-	-	NA	NA
	4. FIRST AID MEASURES							
In	Inhalation: Remove person to fresh air. If needed, get medical attention.							
Ey	e contact:	Immediately flush eyes with plenty of water for at least 15 minutes, remove contact lenses if any. Seek medical advice.						any.
Sł	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.							
In	gestion:	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.				

7. HANDLING AND STORAGE				
Handling:	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	7	
Physical state	Solid (Beads)	Liquid	Liquid	Liquid	Liquid	Solid (Lyophilized)	Solid (Tablet)	
Color	White	Red	Colourless	Colourless	Colourless	Yellow	White	
Odor	Odorless	Odorless	Odorless	Odorless	Odorless	Odorless	Odorless	
pН	NA	7.5	7.5	7.5	7.5	7.5	NA	
Solubility in water	NA	Miscible	Miscible	Miscible	Miscible	Miscible	Miscible	

None.

None.

#### 10. STABILITY AND REACTIVITY

Stability:

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

Reactivity/Hazardous decomposition products:

Conditions/materials to avoid:

11. TOXICOLOGICAL INFORMATION				
UBC <sup>®</sup> 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			

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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.

UBC<sup>®</sup> 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 fore 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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