

### So iSECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
 Product name : Mediagnost RIA II

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Industrial/Professional use spec : Industrial  
 Professional  
 Use of the substance/mixture : Tracer

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

Mediagnost Gesellschaft für Forschung und Herstellung von Diagnostika GmbH  
 Aspenhastraße 25  
 72770 Reutlingen  
 T +49 (0)7121 51484 0 - F +49 (0)7121 51484 10  
[contact@mediagnost.de](mailto:contact@mediagnost.de) - [www.mediagnost.de](http://www.mediagnost.de)

#### 1.4. Emergency telephone number

Emergency number : Mediagnost Gesellschaft für Forschung und Herstellung von Diagnostika GmbH:  
 +49 (0)175 7238099

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

##### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH phrases : EUH210 - Safety data sheet available on request

#### 2.3. Other hazards

No additional information available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Albumins, blood serum	(CAS No) 9048-46-8 (EC no) 232-936-2	< 8	Xn; R22
Sodium phosphate, dihydrate	(CAS No) 10028-24-7 (EC no) 231-448-7	< 1,5	Not classified

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Albumins, blood serum	(CAS No) 9048-46-8 (EC no) 232-936-2	< 8	Acute Tox. 4 (Oral), H302
Sodium phosphate, dihydrate	(CAS No) 10028-24-7 (EC no) 231-448-7	< 1,5	Eye Irrit. 2, H319

# Mediagnost RIA II

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Other hazardous substances: 125J Protein  $\leq$  110 kBq (of the finished product)

Full text of R- and H-phrases: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Allow victim to breathe fresh air.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
First-aid measures after ingestion	: Rinse mouth. Get medical advice/attention.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Foam. Extinguishing powder. Carbon dioxide. Sand. Water spray.  
Unsuitable extinguishing media : Do not use a heavy water stream.

#### 5.2. Special hazards arising from the substance or mixture

No additional information available

#### 5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.  
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

##### 6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.  
Emergency procedures : Ventilate area.

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Collect spillage. Store away from other materials.

#### 6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Hygiene measures : When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Store in dry, cool, well-ventilated area. Keep container closed when not in use.  
Prohibitions on mixed storage : Keep away from food, drink and animal feedingstuffs.

#### 7.3. Specific end use(s)

Tracer.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

# Mediagnost RIA II

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

### 8.2. Exposure controls

Hand protection	: Wear suitable gloves. Nitrile rubber. The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed. Wear protective gloves.
Eye protection	: Safety goggles recommended during refilling.
Skin and body protection	: Protective clothing not absolutely necessary.
Respiratory protection	: Not required.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid for dilution / liquid
Colour	: No data available
Odour	: characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No dangerous reactions known.

### 10.2. Chemical stability

Stable under use and storage conditions as recommended in section 7.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

No hazardous decomposition products known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met

# Mediagnost RIA II

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

#### 12.1. Toxicity

No additional information available

#### 12.2. Persistence and degradability

<b>Mediagnost RIA II</b>	
Persistence and degradability	Not established.

#### 12.3. Bioaccumulative potential

<b>Mediagnost RIA II</b>	
Bioaccumulative potential	Not established.

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Other adverse effects

Other adverse effects	: No other effects known.
	: Do not empty into drains

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods	: Do not empty into drains.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Maximal amount of radioactivity ( $\leq 3$ Bq/g) for Iod 125 in accordance with the German Radiation Protection Ordinance should be considered.
Ecology - waste materials	: Avoid release to the environment.

### SECTION 14: Transport information

In accordance with ADR / IMDG /IATA - Classification of consignments with an activity limit of  $> 1 \cdot 10^6$  Bq (Iod 125).

Consignments with an activity limit of  $\leq 1 \cdot 10^6$  Bq (Iod 125) are not classified as dangerous goods and not subject to the provisions of ADR / IMDG / IATA. Within one and the same consignment maximal 9 finished products á  $1,1 \cdot 10^5$  Bq can be sent without classification.

#### 14.1. UN number

UN-No. (ADR)	: 2910
UN-No.(IATA)	: 2910
UN-No. (IMDG)	: 2910

#### 14.2. UN proper shipping name

Proper Shipping Name (ADR)	: RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL
Proper Shipping Name (IATA)	: RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL
Proper Shipping Name (IMDG)	: RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL
Transport document description (ADR)	: UN 2910 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL, 7, (E)

# Mediagnost RIA II

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

### 14.3. Transport hazard class(es)

Class (ADR)	: 7
Class (IMDG)	: 7
Subsidiary risk (IMDG)	: SP290
Class (IATA)	: 7
Hazard labels (IATA)	: 7
Danger labels (IMDG)	: 7

### 14.4. Packing group

Not applicable

### 14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available.

### 14.6. Special precautions for user

#### 14.6.1. Overland transport

Special provisions (ADR)	: 290, 325
Transport category (ADR)	: 4
Tunnel restriction code (ADR)	: E
Limited quantities (ADR)	: 0
Excepted quantities (ADR)	: E0

#### 14.6.2. Transport by sea

Special provisions (IMDG)	: 290, 325
Limited quantities (IMDG)	: 0
Excepted quantities (IMDG)	: E0
Packing instructions (IMDG)	: 4.1.9
EmS-No. (Fire)	: F-I
EmS-No. (Spillage)	: S-S
Stowage category (IMDG)	: A

#### 14.6.3. Air transport

CAO packing instructions (IATA)	: See 10.3
PCA Limited quantities (IATA)	: Forbidden
Special provisions (IATA)	: A23, A130
ERG code (IATA)	: 7L

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions  
Contains no substance on the REACH candidate list

#### 15.1.2. National regulations

##### Germany

Water hazard class (WGK)	: 1 - low hazard to waters
WGK remark	: Classification based on the components in compliance with Verwaltungsvorschrift wassergefährdender Stoffe (VwVwS)
Storage class (LGK)	: LGK 13 - Non-combustible solids

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

## SECTION 16: Other information

# Mediagnost RIA II

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed
H319	Causes serious eye irritation
R22	Harmful if swallowed
Xn	Harmful

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*