

Safety data sheet

This safety data sheet complies with requirements of Regulation (EU) n° 453/2010 amending Regulation (EC) n° 1907/2006

Rheumatoid Factor Gold reagent (R2) Tris buffer (R1)

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product : Tris buffer (R1)
Rheumatoid Factor Gold reagent (R2)

Code : TRBUF (R1)
RFCOL-H or B or C (R2)

System : 2 reagents ready for use

1.2. Relevant identified uses of the mixture and uses advised against

Laboratory reagents for in vitro diagnostic use

1.3. Details of the supplier of the safety data sheet

Supplier : DiAgam S.A. – Operating headquarters
Rue du Parc industriel
B- 7822 Ghislenghien
Belgium
Phone : + 32.68.55.14.82 Fax : +32.68.56.89.40
mail@diagam.com

1.4. Emergency telephone number

Poison Center Belgium : +32 70 245 245

2. HAZARDS IDENTIFICATION

2.1. Classification of the mixture

This mixture is not classified as dangerous according to Regulation (EC) N° 1272/2008.

2.2. Label elements

The product is not subject to identification regulations under EC Directives.
The usual precautions taken when handling chemicals should be observed.

2.3. Other hazards

PBT : Not applicable
vPvB : Not applicable
none

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3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Human IgG ($\pm 60 \mu\text{g/ml}$) coated on colloidal gold particles suspended in veronal buffer, stabilizers and sodium azide ($< 1\text{g/L}$).

Substances contributing to hazards but present at a lower concentration than meets the criteria for classification of the mixture in accordance with Regulation (EC) N° 1272/2008.

Components	Index-No	EC-No	CAS-No	REACH-No	Weight %	Classification	
Triton™ X-100	-	-	9002-93-1	-	1.0%	Acute Tox. 4; Eye Irrit.2; Aquatic Chronic 2	H302 H319 H411
Barbital sodium	-	205-613-9	144-02-5	-	1.0%	Acute Tox. 4;	H302
Sodium azide	011-004-00-7	247-852-1	26628-22-8	-	< 0.1%	Acute Tox. 2 Acute Tox. 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H300 H310 H373 H400 H410 H412

For the full text of the H-Statements and R-Phrases mentioned in this Section, refer to Section 16.

4. FIRST AID MEASURES

4.1. Description of first aid measures

- General advice :** Show this safety data sheet to the doctor in attendance.
- Inhalation :** Move to fresh air. In case of disorder, seek medical attention.
- Skin contact :** Wash skin with water thoroughly or use a shower. In case of skin irritation or allergic reactions see a physician.
- Eye contact:** Wash eyes with water for at least 15 minutes. In case of disorder, seek medical attention.
- Ingestion :** Seek medical attention immediately.

4.2. Most important symptoms and effect, both acute and delayed

No information available.

4.3. Indication of immediate medical attention and special treatment needed

No information available.

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5. FIREFIGHTING MEASURES

5.1. Extinguishing media

No restriction. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2. Special hazards arising from the mixture

No decomposition products or gases harmful to health to consider in large quantities.

5.3. Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. See Section 8.

6.2. Environmental precautions

Waste disposal must be in accordance with appropriate regulations.
Potentially infectious materials should be autoclaved or incinerated.

6.3. Methods and material for containment and cleaning up

Soak up with absorbent material. Wipe up with absorbent material (e.g. tissue, paper towels).
Clean with water.

6.4. Reference to other sections

For personal protection and disposal see Sections 8 and 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Wear disposable gloves while handling reagents and samples. Thoroughly wash hands afterwards.

7.2. Conditions for safe storage, including any incompatibilities

Storage: store at 2-8°C (R1) and 2-8°C (R2) in the original container.
Incompatibility: No restriction.

7.3. Specific end use(s)

No additional relevant information available.



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8. EXPOSURE CONTRÔL/PERSONAL PROTECTION

8.1. Control parameters

Component	CAS-No	Value	Control Parameters	Base
Sodium azide	26628-22-8	TWA	0.1 mg/m ³	Time weight average
		Identifies the possibility of significant uptake through the skin		
		STEL	0.3 mg/m ³	Short-term exposure
		Identifies the possibility of significant uptake through the skin		
		TGG 8 hr	0.1 mg/m ³	Value for professional exposure
TGG 15 min	0.3 mg/m ³	Value for professional exposure		

8.2. Exposure controls

Appropriate engineering controls: Handle in accordance with good industrial hygiene and safety practice.

Eye/face protection: Wear safety glasses.

Skin/hand protection: Wear disposable gloves while handling reagents and samples. Thoroughly wash hands afterwards. Change contaminated clothing.

Respiratory protection: No personal respiratory protective equipment normally required.

Environmental exposure controls: No information available.

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9. PHYSICAL ET CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Reagent R1

Appearance:	color-free liquid
Odour :	odourless
Odour threshold :	No data available
pH :	+/- 8.0 (20°C)
Melting point/ freezing point :	No data available
Initial boiling point and boiling range :	No data available
Flash point :	No data available
Evaporation rate :	No data available
Flammability (solid, gas) :	No data available
Upper/lower flammability or explosive limits:	No data available
Vapour pressure :	No data available
Vapour density :	No data available
Relative density :	No data available
Solubility(ies) :	Fully miscible in water
Partition coefficient n-octanol/water :	No data available
Auto-ignition temperature :	No data available
Decomposition temperature :	No data available
Viscosity :	No data available
Explosive properties :	No data available
Oxidizing properties :	No data available

Reagent R2

Appearance:	red liquid
Odour :	odourless
Odour threshold :	No data available
pH :	+/- 8.0 (20°C)
Melting point/ freezing point :	No data available
Initial boiling point and boiling range :	No data available
Flash point :	No data available
Evaporation rate :	No data available
Flammability (solid, gas) :	No data available
Upper/lower flammability or explosive limits:	No data available
Vapour pressure :	No data available
Vapour density :	No data available
Relative density :	No data available
Solubility(ies) :	Fully miscible in water
Partition coefficient n-octanol/water :	No data available
Auto-ignition temperature :	No data available
Decomposition temperature :	No data available
Viscosity :	No data available
Explosive properties :	No data available
Oxidizing properties :	No data available

9.2. Other information

No further relevant information available.

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10. STABILITY AND REACTIVITY

10.1. Reactivity

No decomposition if used according to specifications.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

None in the specified conditions of use.

This product contains sodium azide. Sodium azide solutions are reported to react with certain metals (copper, lead, silver, brass) to form explosive metal azide compounds.

10.4. Conditions to avoid

Modification of storage temperature.

10.5. Incompatible materials

No further information available.

10.6. Hazardous decomposition products

No data available.

11. TOXICOLOGICAL INFORMATION – INFORMATION ON TOXICOLOGICAL EFFECTS

Intoxication has so far not become known.

Toxicological data on this product are not available. It contains sodium azide as a preservative, it can be harmful if swallowed. It can irritate the respiratory system.

The preparation may cause irritation of the eyes and skin. Prolonged or repeated exposure may cause nausea and dizziness. To our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1. Toxicity

Ecological data of this product are not available.

When the product is handled and used with care and attention, there is no risk of environmental problems.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

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12.4. Mobility in soil

No data available.

12.5. Results of PBT et vPvB assessment

No data available.

12.6. Other adverse effects

NaN₃ is toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

13. DISPOSAL CONSIDÉRATIONS

13.1. Waste treatment methods

Chemicals residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the concerned country. To ensure compliance we recommend that you contact the relevant (local) authorities and/or approved waste-disposal company for information.

14. TRANSPORT INFORMATION

14.1. UN number

None

14.2. UN proper shipping name

None

14.3. Transport hazard class(es)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

Not applicable

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

Not applicable

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15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulation/legislation specific for the mixture

This product has not to be labeled in accordance with the Regulation (EC) N° 1272/2008.
The usual precautions should be observed when handling chemicals.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed.

16. OTHER INFORMATION

Indication of where changes have been made to the previous version of the safety data sheet:

Modification of the safety data sheet to refer to the Regulation (EC) N° 1272/2008.

No change hazards.

Text of H-codes and R-phrases mentioned in Section 3:

H302	Harmful if swallowed
H319	Causes serious eye irritation
H411	Toxic to aquatic life with long lasting effects
H300	Fatal if swallowed
H400	Very toxic to aquatic organisms
H410	Very toxic to aquatic life with long lasting effects
H310	Fatal in contact with skin
H373	May cause damage to organs through prolonged or repeated exposure if swallowed
H412	Harmful to aquatic life with long lasting effects

This information is based on our present state of knowledge. The purpose of this safety data sheet is to describe the products in terms of their safety requirements. The data does not signify any warranty with regard to the products' properties.

The above information does not to be all inclusive and should be used only as a guide.

DiAgam shall not hold for any damage resulting from handling or use of the product.

The recipient of our product is responsible for observing all applicable laws and regulations.