Safety data sheet

This safety data sheet complies with the requirements of Regulation (EC) No 1907/2006 (REACH), Annex II, as amended by Regulation (EU) No 2020/878.

RHEUMATOID FACTOR

1 SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Product identifier

Product: Rheumatoid factor

Code : **Kit:** RFCOL-B00, RFCOL-H00, RFCOL-C00, RFCOL-B00/ADV, RFCOL-H00/ADV, RFCOL-C00/ADV, RFCOL-B00/ALI, RFCOL-H00/ALI, RFCOL-B00/ARC, RFCOL-H00/ARC, RFCOL-B00/ATE, RFCOL-H00/ATE, RFCOL-B00/AU, RFCOL-H00/AU, RFCOL-B00/COB, RFCOL-H00/COB, RFCOL-B00/UDA, RFCOL-H00/UDA, RFCOL-L00/UDA, RFCOL-B00/IDS 49295.
Bulk: RFCOL-XXX + TRBUF-XXX.

System: ready-made reagents consisting of R1 and R2
R1 => TRBUF-XXX - Tris Buffer
R2 => RFCOL-XXX - Human rheumatoid factor gold reagent

1.2 Relevant identified uses of the mixture and uses advised against

Laboratory reagents for in vitro diagnostics.
For professional users only

1.3 Information on the supplier of the safety data sheet

Company: DiAgam S.A. – Place of business
Rue du Parc industriel 40
B- 7822 Ghislenghien
Belgium
Telephone: 32.68.55.14.82
Fax: 32.68.56.89.40
Contact: Aurélien Morleghem
E-mail: mail@diagam.com

1.4 Emergency contact number

Anti-poison centre (Belgium) : + 32 70 245 245

2 SECTION 2: HAZARD ASSESSMENT

2.1 Classification of the mixture

This mixture is not classified as dangerous under Regulation (EC) No 1272/2008.

2.2 Labelling elements

The product is not required to be identified in accordance with Regulation (EC) No 1272/2008.
The usual precautions should be observed when handling chemicals.

2.3 Other hazards

PBT: Not applicable
vPvB: Not applicable

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3 SECTION 3: COMPOSITION / INFORMATION ON COMPONENTS

3.1 Substances

Does not apply

3.2 Mixtures

3.2.1 Reagent R1

Hazardous substances but present at a concentration lower than that meeting the criteria for classification of the mixture in accordance with Regulation (EC) No 1272/2008.

Components	Index-No	CE-No	CAS-No	REACH -No	Concentration	Classification	
Azoture de sodium	011-004-00-7	247-852-1	26628-22-8	-	0,09	Acute Tox. 2; Acute Tox. 1; STOT RE 2; Aquatic Acute 1; Aquatic Chronic 1.	H300 H310 H373 H400 H410

For the full text of abbreviations, see section 16.

3.2.2 Reagent R2

Component	Index-No	CE-No	CAS-No	REACH-No	Concentration - %w/w	Classification	
Barbitale de sodium	-	205-613-9	144-02-5	-	0,94	Acute Tox. 4; Xn,	H302

4 SECTION 4: FIRST AID

4.1 Description of first aid

General advice: Show this safety card to the doctor during the consultation.

Inhalation: Expose to fresh air. In case of problems, consult a doctor.

Contact with skin: Wash skin thoroughly with water or shower. If skin irritations or allergic reactions occur, seek medical attention.

Contact with eyes: Rinse thoroughly with water for at least 15 minutes.
Remove contact lenses.
If symptoms persist, consult a doctor.

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Ingestion: Rinse your mouth immediately and take deep breaths.
Do not give milk or alcoholic beverages.
If symptoms persist, consult a doctor.

4.2 Main symptoms and effects, both acute and delayed

Unknown.

4.3 Indication of any immediate medical attention and special treatment required

All first aid or treatment should be given as directed by a doctor.

5 SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinction measures

Appropriate measures: No restrictions. Use appropriate extinction methods depending on the environment.

Appropriate measures: N/A.

5.2 Specific hazards arising from the mixture

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

5.3 Advice for firefighters

Wear self-contained protective fire-fighting apparatus if necessary.

6 SECTION 6: MEASURES TO TAKE IN CASE OF ACCIDENTAL SPILLAGE

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. See point 8.

6.2 Environmental precautions

The disposal of waste must be carried out in accordance with regulations in force. Potentially infectious material must be sterilised or incinerated.

6.3 Methods and materials for containment and cleaning

For cleaning: Wipe with absorbent material (e.g. cloth, paper towels). Clean with water.

For containment: Put in a closed container suitable for disposal.

Other information: N/A.

6.4 Reference to other sections

For the protection of workers and disposal, refer to No. 8 and 13.

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7 SECTION 7: HANDLING AND STORAGE

7.1 Precautions to take for safe handling

Protective measures:
Wear disposable gloves when handling reagents and test samples. Wash your hands thoroughly afterwards.
Do not smoke, drink or eat in hazardous areas.

Protective measures intended to prevent fires:
Normal fire prevention measures

Measures intended to prevent the production of particulates and dust:
Put in a closed container suitable for disposal.

Other information:
Wear disposable gloves when handling reagents and test samples. Wash your hands thoroughly afterwards.

7.2 Conditions required for safe storage, taking into account any incompatibilities

Technical measure and storage conditions:	Store at 2-25°C (R1) and 2-8°C (R2) in the original packaging.
Packaging materials:	Original packaging.
Requirement concerning storage premises:	Keep away from heat and sources of ignition
Storage class:	Non-combustible liquid.
Incompatibilities:	No restrictions.

7.3 Specific end use

Laboratory chemicals

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8 SECTION 8: EXPOSURE CONTROL / INDIVIDUAL PROTECTION

8.1 Control parameters

8.1.1 Reagent R1

Component	CAS-No	Value	Control parameters	Base
Sodium azide	26628-22-8	TWA	0.1 mg/m3	Average exposure limit rectified in relation to time
		Identifies the possibility of significant absorption through the skin Indicative		
		STEL	0.3 mg/m3	Short-term exposure limit
		Identifies the possibility of significant absorption through the skin Indicative		
		TGG 8 hr	0.1 mg/m3	Professional exposure values
		TGG 15 min	0.3 mg/m3	Professional exposure values

8.1.2 Reagent R2

N/A.

8.2 Exposure controls

Appropriate technical controls: Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and at the end of the working day.

Protecting the eyes / face: Wear safety goggles.

Protecting the skin: Wear an apron.

Protecting the hands: Wear disposable gloves when handling reagents and test samples. Wash your hands thoroughly afterwards. Change contaminated clothing.

Protecting skin other than the hands: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the workplace.

Respiratory protection: No personal respiratory protective equipment is normally required.

Exposure controls related to environmental protection:

Avoid further spills or leaks, if this is possible safely. Do not let product enter drains. All littering must be avoided in the environment.

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9 SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Essential information on physical and chemical properties

Reagent R1

Physical state:	liquid
Color:	colourless
Odor :	odourless
Melting point/freezing point:	data not available
Initial boiling point and boiling range:	data not available
Flammability:	data not available
Upper/lower explosivity limits:	data not available
Flash point:	data not available
Auto-ignition temperature:	data not available
Decomposition temperature:	data not available
pH:	+/- 8.00 (20°C)
Viscosity :	data not available
Solubility:	Water soluble
Partition coefficient n-octanol/water:	data not available
Vapour pressure:	data not available
Relative density:	data not available
Relative vapour density:	data not available
Characteristics of particles:	data not available

Reagent R2

Physical state:	liquid
Coulor:	red wine
Odor :	odourless
Melting point/freezing point:	data not available
Initial boiling point and boiling range:	data not available
Flammability:	data not available
Upper/lower explosivity limits:	data not available
Flash point:	data not available
Auto-ignition temperature:	data not available
Decomposition temperature:	data not available
pH:	+/- 8.00 (20°C)
Viscosity :	data not available
Solubility:	Water soluble
Partition coefficient n-octanol/water:	data not available
Vapour pressure:	data not available
Relative density:	data not available
Relative vapour density:	data not available
Characteristics of particles:	data not available

9.2 Other information

Reagent R1

Flammability	Not flammable
Self-ignition	N/A.

Reagent R2

Flammability	Not flammable
Self-ignition	N/A.

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10 SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No decomposition if correctly used.

10.2 Chemical stability

Stable under the recommended storage conditions.

10.3 Possibility of hazardous reactions

None under the specified conditions of use.
This product contains sodium azide: Sodium azide becomes explosive on contact with heavy metals such as copper or lead.

10.4 Conditions to avoid

Changing the storage temperature (except transport).

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

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11 SECTION 11: TOXICOLOGICAL INFORMATION - INFORMATION ON TOXICOLOGICAL EFFECTS

11.1 Reagent R1

Component: SODIUM AZIDE

Acute toxicity
DL50 Oral - Rat - > 2,000 mg/kg.

Skin corrosion/skin irritation
Skin - Rabbit
Result: No irritation of the skin.
(OECD guideline 404.)

Serious eye damage/eye irritation
Skin - Rabbit
Result: No irritation of the eyes.
(OECD guideline 405.)

Respiratory or skin sensitisation
Data not available.

Germ cell mutagenicity
Data not available.

Carcinogenicity
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or recognised as carcinogenic for humans by IARC.

Toxicity for reproduction
Data not available.

Specific target organ toxicity - single exposure
Data not available.

Specific target organ toxicity - repeated exposure
Data not available.

Aspiration hazard
Data not available.

Endocrine disrupting properties
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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Additional information
RTECS: AH4410000
To the best of our knowledge, the chemical, physical and toxicological properties have not been fully investigated.

11.2 Reagent R2

Component: Sodium barbital

Acute toxicity
DL50 Oral - Rat - 600 - 600 mg/kg
DL50 Intraperitoneal - rabbit - 250 mg/kg
Skin corrosion/skin irritation
data not available
Serious eye damage/eye irritation
data not available
Respiratory or skin sensitisation
Germ cell mutagenicity
Carcinogenicity
Carcinogenicity - rat – Oral
Tumorigenic: Neoplastic according to RTECS Kidney, Ureter, Bladder criteria: Kidney tumours
Carcinogenicity - rat – Oral
Tumorigenic: Tumorigenic according to RTECS Kidney, Ureter, Bladder criteria: Kidney tumours
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or recognised as carcinogenic for humans by IARC.

Toxicity for reproduction

Reproductive toxicity - rat – Intraperitoneal

Consequences on fertility: Other fertility measures
Reproductive toxicity - rat - Subcutaneous.

Consequences on fertility: Post-implant mortality (e.g. implants that are dead and/or resorbed by the total number of implants). Fertility consequences: litter size (e.g. foetus per litter, size before birth). Implications for the embryo or the foetus: Fetotoxicity (except death, e.g. foetal rickets)
Reproductive toxicity - rat - Subcutaneous.

Maternal effects: Ovaries, fallopian tubes.
Reproductive toxicity - rat - Subcutaneous.
Consequences on paternity: Prostate, seminal vesicle, Cowper's gland, accessory glands.

Reproductive toxicity - rat - not reported.
Consequences on new-born. Behavioural effect.
Developmental toxicity - mouse - Intraperitoneal.

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Specific development malformations. Central nervous system malformations.

Development specifics: Skeletal muscle system.

Developmental toxicity - mouse - Intraperitoneal.

Specific development malformations. Cranofacial (especially the nose and tongue).

Specific target organ toxicity - single exposuredata not available

Specific target organ toxicity - repeated exposure
Data not available.

Aspiration hazard
Data not available.

Endocrine disrupting properties
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional information
Acute symptoms of overexposure include: sedation, hypnosis. Any exposure to large amounts may cause: coma. Any prolonged or repeated exposure may cause: addiction.

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12 SECTION 12: ECOLOGICAL INFORMATION

12.1 Reagent R1

12.1.1 Toxicity

Component: SODIUM AZIDE

Toxicity for fish:
mortality CL50 - Pimephales promelas (Fathead minnow) - 5.46 mg/l - 96 h
(OECD guideline 203.)
Toxicity for algae:
CE50 statistic test - Pseudokirchneriella subcapitata - 0.35 mg/l - 96 h.
(OECD guideline 201.)

12.1.2 Persistence and degradability

Result: - Readily biodegradable.

12.1.3 Bioaccumulative potential

Data not available.

12.1.4 Mobility in soil

Data not available.

12.1.5 Results of PBT and vPvB assessments

This substance/mixture contains no ingredient considered persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or more.

12.1.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.1.7 Other adverse effects

Very harmful to aquatic life, causes long-term adverse effects.

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12.2 Reagent R2

Component: Sodium Barbital

12.2.1 Toxicity
N/A.

12.2.2 Persistence and degradability
N/A.

12.2.3 Bioaccumulative potential
N/A.

12.2.4 Mobility in soil
N/A.

12.2.5 Results of PBT and vPvB assessments
The PBT / vPvB assessment is not available because the chemical safety assessment is not required / not conducted.

12.2.6 Endocrine disrupting properties
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.2.7 Other adverse effects
N/A.

13 SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste processing methods
Chemical waste should be systematically treated as special waste.
This must be disposed of in accordance with the anti-pollution laws of the country concerned. To ensure compliance, we recommend contacting (local) authorities and / or a licensed waste disposal company.

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14 SECTION 14: INFORMATION CONCERNING TRANSPORT

14.1 UN number or identification number

Not registered as dangerous products.

14.2 United Nations shipping name

Not registered as dangerous products.

14.3 Hazard class for transport

Not registered as dangerous products.

14.4 Packaging group

Not registered as dangerous products.

14.5 Dangers for the environment

Not registered as dangerous products.

14.6 Specific precautions to be taken by the user

Not registered as dangerous products.

14.7 Maritime transport in bulk according to IMO instruments

Not registered as dangerous products.

15 SECTION 15: REGULATORY INFORMATION

15.1 Safety regulations/legislation specific to health, safety, and the environment

The product is not required to be identified in accordance with Regulation (EC) No 1272/2008.
The usual precautions should be observed when handling chemicals.

15.2 Chemical safety assessment

No chemical safety assessment required.

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16 SECTION 16: OTHER INFORMATION

Change to the safety data sheet since the latest version:
Change to the safety data sheet to meet requirements of Regulation (EC) n° 1907/2006 (REACH), Annex II, as amended by Regulation (EU) No 2020/878.

No change in hazards.

H codes and abbreviations mentioned in section 3

Acute tox.	Acute toxicity
Aquatic acute	Acute toxicity for the aquatic environment
Aquatic chronic	Chronic toxicity for the aquatic environment
H300	Fatal if ingested
H300 + H310	Fatal if ingested or through skin contact
H302	Harmful if ingested
H310	Fatal through skin contact
H332	Harmful if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure by inhalation.
H400	Very harmful to aquatic life
H410	Very harmful to aquatic life, causes long-term adverse effects.
STOT RE	Specific target organ toxicity - Repeated exposure
Xn	Harmful

This information is based on our current knowledge. The purpose of this safety data sheet is to describe the products according to their safety requirements but are provided without warranty of any kind. The above information is not exhaustive and should be used only as a guide. DiAgam is not responsible for any damage resulting from the handling or use of the product.
The recipient of this product is responsible for compliance with all applicable laws and regulations.

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