

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.

PREALBUMIN

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

1.1 Product identifier

Product: Prealbumin

Code : **Kit:** PATUR-B00, PATUR-H00, PATUR-B00/ADV, PATUR-H00/ADV, PATUR-C00/ADV, PATUR-B00/ALI, PATUR-H00/ALI, PATUR-L00/ALI PATUR-H00/ARC, PATUR-B00/ATE, PATUR-H00/ATE, PATUR-C00/ATE, PATUR-B00/AU, PATUR-H00/AU, PATUR-B00/COB, PATUR-H00/COB, PATUR-H00/CGR.

Bulk: PATUR-XXX + I7BUF-XXX.

System: ready-made reagents consisting of R1 and R2
R1 => I7BUF-XXX - Imidazole Buffer
R2 => PATUR-XXX - Human anti-prealbumin anti-serum

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	
Imidazole	01-2119485825-24-XXXX	206-019-2	288-32-4	-	0.24	Acute Tox. 4; Skin Corr. 1; Repr 1B;	H302 H314 H360D
Sodium azide	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

N/A.

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

Imidazole			
Application area	Exposure routes	Health effects	Value
Workers	Inhalation	Long term - systemic effects	10.6 mg/m ³
Workers	Contact with skin	Long term - systemic effects	1.5 mg/kg PC/j

Component	CAS-No	Value	Control parameters	Base	
Sodium azide	26628-22-8	TWA	0.1 mg/m ³	Average exposure limit rectified in relation to time	
		Identifies the possibility of significant absorption through the skin Indicative			
		STEL	0.3 mg/m ³	Short-term exposure limit	
		Identifies the possibility of significant absorption through the skin Indicative			
		TGG 8 hr	0.1 mg/m ³	Professional exposure values	
		TGG 15 min	0.3 mg/m ³	Professional exposure values	

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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:	+/- 7.00 (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
Color:	yellow
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:	+/- 7.40 (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: IMIDAZOLE

Acute toxicity

DL50 Oral - Rat - > 970 mg/kg.

Skin corrosion/skin irritation

Skin - Rabbit

Result: Corrosive, category 1C - reactions observed after exposure from one to four hours and an observation period of up to 14 days.

Serious eye damage/eye irritation

Data not available.

Respiratory or skin sensitisation

Data not available.

Germ cell mutagenicity

Animal experiments have not shown any mutagenic effects. Tests on bacterial or mammalian cell cultures have revealed no mutagenic effects.

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

May harm foetus.

May be toxic to humans in reproduction. May harm foetus.

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

N/A.

Additional information

RTECS: NI3325000

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To the best of our knowledge, the chemical, physical and toxicological properties have not been fully investigated.

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

Acute toxicity

N/A.

Skin corrosion/skin irritation

N/A.

Serious eye damage/eye irritation

N/A.

Respiratory or skin sensitisation

N/A.

Germ cell mutagenicity

N/A.

Carcinogenicity

N/A.

Toxicity for reproduction

N/A.

Specific target organ toxicity - single exposure

N/A.

Specific target organ toxicity - repeated exposure

N/A.

Aspiration hazard

N/A.

Endocrine disrupting properties

N/A.

Additional information

N/A.

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12 SECTION 12: ECOLOGICAL INFORMATION

12.1 Reagent R1

12.1.1 Toxicity

Component: IMIDAZOLE

Toxicity for fish:

CL50 statistic test - *Leuciscus idus*(Ide) - > 280 mg/l - 48 h.

Toxicity to daphnia and other aquatic invertebrates:

CE50 - *Daphnia* - > 341.5 mg/l - 48 h.

Toxicity for algae:

CL50 statistic test - *Scenedesmus quadricauda* (green algae) - > 133 mg/l - 72 h

Toxicity for bacteria:

see user-created text - other microorganisms - 45 mg/l - 0.5 h

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

aerobic - Exposure duration 19 d
Result: 86% - 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

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

N/A.

12.2.6 Endocrine disrupting properties

N/A.

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
EUH032	When in contact with an acid, gives off a very toxic gas
Eye dam.	Serious eye damage/eye irritation
H300	Fatal if ingested
H300 + H310	Fatal if ingested or through skin contact
H302	Harmful if ingested
H310	Fatal through skin contact
H315	Causes skin irritation
H318	Causes serious skin damage.
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.
H411	Very harmful to aquatic life, causes long-term adverse effects.
H412	Harmful to aquatic life, causes long-term adverse effects.
N	Dangerous for the environment
Skin irrit.	Skin corrosion/skin irritation
STOT RE	Specific target organ toxicity - Repeated exposure
T+	Very toxic
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.