

Safety data sheet

This safety data sheet complies with the requirements of Regulation (EU) No 453/2010 amending Regulation (EC) No 1907/2006

CALIBRATORS & CONTROLS FIBRINOGEN

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

1.1 Product identifier

Product: Calibrators & controls Fibrinogen

Code :

Product	Code
Calibrator Fibrinogen	FIREM
Control Fibrinogen	FICON

1.2 Relevant identified uses of the mixture and uses advised against

Laboratory reagents for in vitro diagnostics

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

None

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3 SECTION 3: COMPOSITION / INFORMATION ON COMPONENTS

3.1 Substances

Does not apply

3.2 Mixtures

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	CAS-No	Weight %
Human plasma	NA	> 99%
Non-hazardous buffers and / or stabilizers	NA	< 1%

For the full text of abbreviations, see section 16.

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.
- 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.

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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

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

Appearance:	Yellow liquid
Smell:	odourless
Odour threshold:	data not available
pH:	6.5 – 7.5
Melting point/freezing point:	data not available
Initial boiling point and boiling range:	data not available
Flash point:	data not available
Evaporation rate:	data not available
Flammability (solid, gas):	data not available
Upper/lower flammability limits or Explosivity limits:	data not available
Vapour pressure:	data not available
Vapour density:	data not available
Relative density:	data not available
Solubility:	Water soluble:
Partition coefficient: n-octanol/water:	data not available
Auto-ignition temperature:	data not available
Decomposition temperature:	data not available
Viscosity:	data not available
Explosive properties:	data not available
Oxidising properties:	data not available

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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 Toxicity

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

Additional information

N/A

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12 SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Toxicity
N/A

12.1.2 Persistence and degradability
N/A

12.1.3 Bioaccumulative potential
N/A

12.1.4 Mobility in soil
N/A

12.1.5 Results of PBT and vPvB assessments
N/A

12.1.6 Other adverse effects
N/A

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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.

14 SECTION 14: INFORMATION CONCERNING TRANSPORT

14.1 UN 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 Transport in bulk in accordance with Annex II of MARPOL 73/78 and the IBC Code

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 refer to the adequacy of the safety data sheet in relation to Regulation (EC) No 1272/2008.

No change in hazards.

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.