

Safety data sheet

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

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

1.1. Product identifier

Product	Code
Fibrinogen Medium Level Calibrator	FIREM
Fibrinogen Control	FICON

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 Parcindustriel
B- 7822 Ghislenghien
Belgium
Telephone : + 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

General hazard information: Human biological fluid. Potential biohazard. Handle in accordance with good industrial hygiene. Full safety precautions should be taken as in handling any potentially infected body fluid. May cause eye, skin, and respiratory tract irritation. The toxicological properties have not been fully investigated.

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

Components	CAS-No	Weight %
Human Plasma	NA	> 99%
Non-hazardous Buffers and/or Stabilizers	NA	< 1%

4. FIRST AID MEASURES

4.1. Description of first aid measures

- General advice :** Show this safety data sheet to the doctor in attendance.
Treat symptomatically.
- Inhalation :** Move to fresh air. If breathing is difficult, give oxygen. Get medical attention immediately if symptoms occur.
- Skin contact :** Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.
- Eye contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
- Ingestion :** Do not induce vomiting. Obtain 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.

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.



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6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes and clothing. See Section 8.

6.2. Environmental precautions

Waste disposal must be in accordance with appropriate regulations. Should not be released into the environment.

Potentially infectious materials should be autoclaved or incinerated.

6.3. Methods and material for containment and cleaning up

Avoid dust formation. Sweep up or vacuum up spillage and collect in suitable container for disposal. Dispose of cleanup material in marked biohazard container.

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

Handle as potentially infectious. Handle in accordance with good industrial hygiene and safety practice. Wear personal protective equipment. Ensure adequate ventilation. Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothing. Thoroughly wash hands afterwards.

7.2. Conditions for safe storage, including any incompatibilities

Storage: store at 2-8°C in the original container. Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatibility: No restriction.

7.3. Specific end use(s)

No additional relevant information available.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1. Control parameters

8.2. Exposure controls

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

Eye/face protection: Wear safety glasses.

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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.

9. PHYSICAL ET CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Buff - yellow
Odour :	Odourless
Odour threshold :	No data available
pH :	6.5 – 7.5
Melting point/ freezing point :	No data available
Initial boiling point and boiling range :	No data available
Flash point :	No applicable
Evaporation rate :	No data available
Flammability (solid, gas) : 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 under normal processing.

10.4. Conditions to avoid

Modification of storage temperature. Avoid dust formation. Excess heat.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Thermal decomposition can lead to release of irritating gases and vapors.

11. TOXICOLOGICAL INFORMATION – INFORMATION ON TOXICOLOGICAL EFFECTS

Intoxication has so far not become known.

Toxicological data on this product are not available. It can irritate the respiratory system, may be harmful if inhaled. The preparation may cause irritation of the eyes and skin. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. 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.

12.4. Mobility in soil

No data available.

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12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

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.

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.