ARENA BioScien

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company

1.1 Product identifier

- Product Name: Fibrinogen

1.2 Relevant identified uses of the substance or mixture and uses advised against

Diagnostic reagent for the in-vitro quantitative determination of plasma Fibrinogen using Clauss Clotting Time method in both automatic and manual systems.

1.3 Details of the supplier of the safety data sheet

- Name of Manufacturer: Arena BioScien, SEA
- Address of Manufacturer: Block 5, Street 9 Ismailia free zone. Ismailia- Egypt
- Telephone: +202 21813500/ +201113102057
- Email: admin@arenabioscientific.com

SECTION 2 Hazards identification

Hazard description:

The reagent is not classified as dangerous. Information concerning particular hazards for human and environment:

Hazard Classification:

the reagent is not hazardous chemical, so this provision does not apply Pathways: ingestion The reagent has no healthy hazards, environmental hazards and blasting danger.

SECTION 3 Composition/information on ingredients

ACTIVE INGREDIENTS

Fibrinogen assay reagent is homogeneous mixture and the hazardous component is Sodium Azide (NaN3) but added in ≤ 0.1 % as a preservatives (below the hazardous classification).

R1: Thrombin Reagent	Bovine Thrombin 100 NIH units/ml liquid ready to use.
R2: Buffer	Owren's buffer**,** ready to use (pH 7.35).
R3: *Fibrinogen calibrator*	lyophilized preparation of human plasma, concentration stated on the vial label.

SECTION 4 First aid measures

Brief treatment for self-help and ambulance needed to be taken when field staff is accidentally injured by the reagent.

(1) Eye contact: The chemicals are hazardous materials, if they accidentally get in the eyes, eyelids should be lifted and flush the eyes with plenty of water.

(2) Ingestion: The chemicals are hazardous materials, if they taken by accident, you should seek medical care immediately.

SECTION 5 Fire-fighting measures

Non-flammable.

Using the reagents according to protocol should not incur a fire or explosion hazard. In case of fire, use water, foam, carbon dioxide, or dry chemical, as suitable for the surrounding fire and materials.

SECTION 6 Accidental release measures

Handling Precautions:

The production process of the reagent is carried out in ten thousand clean areas. Operator must go through specialized training and strictly comply with the operation procedures. Should wear white clean clothes during operation and wear rubber gloves

SECTION 7 Handling and storage

Information for safe handling: Keep out of reach of children.
Storage: Store in the original container at 2-8°C.
Requirements to be met by storerooms and receptacles: No special requirements.

SECTION 8 Exposure controls/personal protection

8.1 Control parameters
- There are no recommended or established controls for this product.

8.2 Exposure controls
- Eyewash bottles should be available.
- Engineering controls should be provided to prevent the need for ventilation.
- No respiratory protection is needed if ventilation/extraction is adequate, otherwise wear approved dust mask, NIOSH N95 (US) or type FFP1 (EN143) dust masks.
- Wear protective gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and standard EN 374.
- Wear safety glasses approved to standard for ANSI Z87 or EN 166.

SECTION 8 Exposure controls/personal protection (continued…)

- Wear suitable protective clothing in accordance with good chemical hygiene practices.



SECTION 9 Physical and chemical properties

9.1 The appearance and shape of the products:
9.1. The lyophilized product of FIB thrombin reagents should be white or slightly yellow loose material; it should be a uniform solution after reconstitution. The liquid reagent of FIB thrombin reagents should be uniform solution.
9.2 pH value: 7.0± 0.5
9.3 Melting point: not applicable
9.4 Boiling point: not applicable
9.5 Relative density (water=1): not available
9.6 Relative vapor density (air=1): not available
9.7 Saturated vapor pressure: not applicable
9.8 Combustion heat: not applicable
9.9 Critical temperature: not applicable
9.10 Critical pressure: not applicable
9.11 Octanol / water partition coefficient: not applicable
9.12 Flash point: not applicable
9.13 Firing temperature (Ignition temperature): not applicable
9.14 Upper explosive limit: not applicable
9.15 Lower explosive limit: not applicable
9.16 Solubility: all 100% soluble in water
9.17 Main application
9.17.2 FIB agents: used for quantitative determination of plasma fibrinogen in clinical, commonly used for the auxiliary diagnosis of congenital and acquired fibrinogen deficiency and monitoring of thrombolytic therapy.

SECTION 10 Stability and reactivity

10.1 Stability:
liquid reagent: stored at 2-8°C. under airtight after opening can be stable for 30 days. Lyophilized reagents: stored at 2-8°C after reconstitution can be stabile for 5 days.
10.2 Conditions to be avoided: heat, cold, light and squeezing
10.3 Materials to be avoid matching with none
10.4 Polymerization hazard: none
10.5 Decomposition products: The Reagent will not produce harmful substances when in combustion or chemical reaction

SECTION 11 Toxicological information

11.1 Information on toxicological effects
- No experimental test data available for the mixture
- Contact with skin: No irritating effects known.
- Contact with eyes: No irritating effects known.
- Carcinogenicity:
Not listed in the National Toxicology Program (NTP) 13th Report on Carcinogens.

SECTION 11 Toxicological information (continued…)

Not found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs, Volumes 1-112.
Not listed in OSHA standard 1910.1003 Carcinogens.
- Mutagenicity: No evidence of mutagenic effects.
- Teratogenicity: No information available

SECTION 12 Ecological information

12.1 Toxicity
- Quantitative data on the toxic effects of this product is not available.
12.2 Persistence and degradability
- The test kit contains plastic and other components that are not readily degradable.
12.3 Bioaccumulation Potential
- No information available
12.4 Mobility in soil
- No information available
12.5 Results of PBT and vPvB assessment
- Not a PBT according to REACH Annex XIII
- PBT/vPvB assessment not available
12.6 Other Adverse Effects
- To the best of our knowledge, the properties of this material have not been fully evaluated.
- On available data, substance is not harmful to the environment.

SECTION 13 Disposal considerations

13.1 Waste nature: the wastes of the reagent is not hazardous wastes
13.2 Waste disposal methods: handed over to professional medical waste disposal company for handling.
13.3 Waste precautions: none

SECTION 14 Transport information

14.1 UN Number
- Not classified as hazardous for transport
14.2 UN Proper Shipping Name
- Not applicable
14.3 Transport hazard class(es)
- Not applicable

14.4 Packing group
- Not applicable

14.5 Environmental hazards
- Not Classified

14.6 Special precautions for user
- Not Classified

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code
- Not Classified

14.8 Domestic Surface Transport (US DOT)
- Proper Shipping Name: Not applicable
- DOT UN No.: Not applicable
- DOT Hazard Class: Not applicable

SECTION 14 Transport information (continued…)

- DOT Packing Group: Not applicable

14.9 International Road/Rail (ADR/RID)
- Proper Shipping Name: Not applicable
- ADR UN No.: Not applicable
- ADR Hazard Class: Not applicable
- ADR Packing Group: Not applicable
- Tunnel Code: Not applicable

14.10 Ocean/Sea (IMO/IMDG)
- Proper Shipping Name: Not applicable
- IMDG UN No.: Not applicable
- IMDG Hazard Class: Not applicable
- IMDG Packing Group: Not applicable

14.11 Air (ICAO/IATA)
- Proper Shipping Name: Not applicable
- ICAO Un No.: Not applicable
- ICAO Hazard Class: Not applicable
- ICAO Packing Group: Not applicable

SECTION 15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- This Safety Data Sheet is provided in compliance with the EC Directive 1907/2006- 453/2010, WHMIS 2015 requirements as specified in the Hazardous Products Act (HPA) and the Hazardous Products Regulations (HPR), and with the OSHA Hazard Communication Standard 29 CFR 1910.1200.

- Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe.

SECTION 16 Other information

Date of Preparation: September 2019
Revision: Rev. 0
Replaces: New issue

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