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

1.1 Product identifier

- Product Name: **D-DIMER**

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

- Diagnostic reagent set (Slide latex tests) for the in-vitro qualitative screening and semi-quantitative for the detection of circulating derivatives of cross-linked fibrin degradative products(XL-FDP) in human plasma.

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

Components contain less than 0.1% wt of Sodium Azide (NaN3) as preservative.

The control component(s) in each of the above products contain(s) materials derived from human or animal sources. The source material used to prepare these controls are tested by an approved method for the presence of human immunodeficiency virus (HIV) as well as for Hepatitis B surface antigen; and only those materials found to be negative (not repeatedly reactive) are used to prepare products for sale.

When used in accordance with the Principles of Good Laboratory Practice, Good Standards of Occupational Hygiene and the instructions stated in the product insert, these products are not considered to present a hazard to health.
Information concerning particular hazards for human and environment:
Under the recommended conditions of use, there is no risk of exposure to any of the materials contained in the test.

SECTION 3 Composition/information on ingredients

3.1 Substances

KIT COMPONENT	INGREDIENT
D-Dimer Latex Reagent	A 0.83% suspension of latex particles coated with murine anti-D-Dimer monoclonal antibody, 10mg/mL BSA and 0.1% sodium azide.
D-Dimer Positive Control	A solution containing purified human D-Dimer fragment, 5mg/mL BSA and 0.1% sodium azide.
Dimer Negative Control	A buffer solution containing 5mg/mL BSA and 0.1% sodium azide.
Dilution Buffer	Ready to use buffer

3.2 Mixtures

- This product does not contain any hazardous substances at the concentration limits given in Regulation (EC) No. 1272/2008 and OSHA Hazard Communication Standard 29 CFR 1910.1200.

SECTION 4 First aid measures

4.1 Description of first aid measures

- General

In case of doubt, or when symptoms persist, seek medical attention.
In general, this product is not hazardous to humans or animals, but like any other chemical, it should be treated with care, respect, and common sense.

SECTION 4 First aid measures (continued…)

- Contact with skin
  Remove contaminated clothing.
  Wash affected area with plenty of soap and water.
  If skin irritation or rash occurs: Get medical advice/attention. Contaminated clothing should be laundered before reuse.
- Contact with eyes
  If substance has gotten into eyes, immediately wash out with plenty of water for at least 15 minutes. Irrigate eyes thoroughly while lifting eyelids. Seek medical advice if necessary.
- Ingestion
  Rinse mouth with water (do not swallow).
  Never make an unconscious person vomit or drink fluids.
  If medical advice is needed, have product container or label at hand.
- Inhalation
  If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

- The most important known symptoms are described in the labeling (see Section 2.2) and/or in Section 11.

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically.

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

Health Hazards:Poison, Do Not Inhale or Swallow.
First Aid Measures:Inhale: Remove to fresh air.
Contact: Flush with water for 15 minutes.
Swallow: If conscious, wash mouth out with water.
Call Physician.

SECTION 7 Handling and storage

7.1 Precautions for safe handling

- The reagents in this kit contain sodium azide as a preservative. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
- It should be noted, however, that there is no guarantee for products derived from human and animal sources not to transmit infectious diseases and thus should be handled with care.
- Keep out of reach of children.

7.2 Conditions for safe storage, including any incompatibilities

- Storage temperature: see component label
- Store in a well-ventilated place. Keep container tightly closed.
- Store in a dry place.
- Keep away from: heat sources, acids.

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



SECTION 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Colour: white latex and Straw controls.
- Odor: No information available
- pH: No information available
- Melting point/Range: No information available
- Boiling Point/Range: Not applicable
- Flashpoint: No information available
- Evaporation Rate: Not applicable
- Flammability: No information available
- Vapor Pressure: No information available
- Vapor Density: No information available
- Specific Gravity: No information available
- Solubility in water: No information available
- Partition Coefficient (n-Octanol/Water): No information available
- Explosive Properties: Product does not present an explosion hazard
- Oxidizing Properties: No information available

9.2 Other information

- No information available

SECTION 10 Stability and reactivity

10.1 Reactivity

- No information available

10.2 Chemical stability

- Considered stable under normal conditions.

10.3 Possibility of hazardous reactions

- No hazardous reactions known if used for its intended purpose.

10.4 Conditions to avoid

- Avoid contact with moisture.
- Keep away from heat and sources of ignition.

SECTION 10 Stability and reactivity (continued…)

10.5 Incompatible materials
- None known

10.6 Hazardous Decomposition Products
- No hazardous decomposition products are formed in high quantities.

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.
  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 treatment methods
- Disposal should be in accordance with local, regional, national, and/or international regulations.
- Do not discharge into drains or the environment, dispose to an authorized waste collection point.
- Do not reuse empty containers.

13.2 Classification (REACH)
- Waste Codes in accordance with the European Waste catalogue (EWC) are origin-defined.

Since this product is used in several industries, no Waste Code can be provided by the supplier. The Waste Code should be determined in arrangement with your waste disposal partner or the responsible authority.

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

SECTION 14 Transport information (continued…)

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
- 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

This document is believed to be correct, but does not purport to be all inclusive and shall be used only as a guide. Arena BioScien Manufacturers, SEA. shall not be held liable for any damage resulting from handling or from contact with the above product. These suggestions should not be confused with state, municipal or insurance requirements, and constitute NO WARRANTY.