ARENA BioScien

Safety Data Sheet

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

1.1 Product identifier

- Product Name: D-DIMER Turbi

1.2 Use of the mixture: For in vitro diagnostic use.

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

2.1 Mixture classification (see also ch. 15)

Classified: not dangerous according to 67/548/EEC and 1999/45/EEC Directives Classified: not hazardous according to 1272/2008/EC Regulation

2.2 Potential health and environmental effects

Ingestion: May be harmful if swallowed.
Inhalation exposure: May cause irritation.
Contact with skin: May cause irritation.
Contact with eyes: May cause irritation.
Sensitization: Might cause sensitization by inhalation or skin contact.
Environmental exposure: Might cause adverse effects for the environment.
Warning: The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

SECTION 3 Composition/information on ingredients

3.1 Substances

KIT COMPONENT	Composition		
D-Dimer Latex Reagent	PBS	0.1	mol/L
	D-Dimer latex	0.1	%
	NaN3	1.0	g/L
Reaction Buffer	PBS	0.1	mol/L
	PEG	4.0	%
	NaN3	1.0	g/L
D-Dimer Calibrator	Lyophilized plasma enriched with D-Dimer. Concentration as stated on the vial label		

- 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

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
Inhalation exposure: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.
Contact with eyes: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

SECTION 5 Fire-fighting measures

Suitable extinguishing means: Water spray or regular foam, CO2, dry powder.
Mean of extinguishing NOT to be used: Not known.
Known hazards caused by combustion: Thermal decomposition or combustion may generate toxic and hazardous fumes (COx, NOx, Na2O, HCl).
Equipment for self-protection: (fire fighters): Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.

SECTION 6 Accidental release measures

Personal precautions: Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.
Environmental precautions: Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.
Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

SECTION 7 Handling and storage

7.1 Handling

Handling procedures: Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas. Work/Hygienic practices: Wash hands with soap and water after use.

7.2 Storage

Room ventilation: Well ventilated workplace.

Special precautions: (see also Section 8) Avoid environmental release. Recommended temperature: Store at 2 – 8°C.

Humidity, light and other environmental factors: Avoid light exposure and keep away from heat sources and non compatible materials.

Containers: Keep containers tightly closed and labelled with the name of the product.
Other storage precautions: Keep away from food and drinks. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

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.


Gloves


Safety Glasses


Lab Coat

SECTION 9 Physical and chemical properties

9.1 General information

Appearance: Liquid
Odor: Odorless
Color: Colorless

9.2 Important health, safety and environmental information

pH: 8.4 – 8.6
Boiling point/range: not available
Flash point: not available
Vapor pressure: not available
Density: not available
Solubility: not available
Water Solubility: miscible
Viscosity: not available
Vapor density: not available
Evaporation rate: not available

9.3 Other information

Melting point/range: not available

SECTION 10 Stability and reactivity

Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.

10.1 Conditions to avoid: Keep out from heat, water, humidity and light.

10.2 Materials to avoid: Strong oxidising agents. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water.

10.3 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of COX, NOX, Na2O, HCl.

SECTION 11 Toxicological information

11.1 Toxicokinetic effects (ADME)

Absorption: Sodium azide is rapidly absorbed from the gastrointestinal tract and from injection sites.
Distribution: not available
Metabolism: not available
Excretion: not available

11.2 Acute toxicity

Oral: LD50 (rat) = 27 mg/Kg Sodium azide
Dermal: LD50 (rat) = 50 mg/Kg Sodium azide
Inhalation: LC50 (rat) = 37 mg/m3 Structural or functional change in trachea or bronchi, effects on eye, convulsions or effect on seizure threshold Sodium azide
Other data: LDLo oral rabbit = not available mg/Kg

11.3 Irritation
Skin: not available
Eye: not available
Inhalation: not available
11.4 Sensitization:
Skin sensitization: not available
Sensitization by inhalation: not available
11.5 Prolonged exposure toxicity: not available
11.6 CMR effects
Mutagenicity:
Ames test: Sodium azide was mutagenic in Salmonella typhimurium strains TA100 and TA1535 with or without exogenous metabolic activation (S9); it was not mutagenic in strain TA1537 or TA98. Sodium azide
Mouse lymphoma: not available
Chromosomal aberration: Negative Sodium azide
Cytogenetic tests with Chinese hamster ovary cells: Sodium azide induced sister chromatid exchanges, but not chromosomal aberrations. (5) Sodium azide Micronucleus test: not available
Teratogenesis: In a teratogenic study employing albino rats treated orally with technical Sodium azide at dose levels of 0.5, 1.5, or 5.0 mg/kg daily during gestation days 6 through 15, no teratogenic effects due to Sodium azide were found. Sterility has been produced in male mice given sodium azide.
Carcinogenesis: Carcinogenicity studies were conducted by administering sodium azide (greater than 99% pure) in distilled water by gavage to groups of male and female rats once daily, 5 days per week for 14 days, 13 weeks, or 2 years. Under the conditions of these 2-year gavage studies, there was no evidence of carcinogenic activity of sodium azide in male or female rats administered 5 or 10 mg/kg. Sodium azide induced necrosis in the cerebrum and the thalamus of the brain in both male and female rats.

SECTION 12 Ecological information

12.1 Ecotoxicology
Acute toxicity with fish: LC50 bluegill fish = 0.7 mg/l/96 hours Sodium azide
Acute toxicity with Daphnia Magna: EC50 daphnia pulex = 4.2 mg/l/96 hours Sodium azide
Acute toxicity with algae: ErC50 = not available mg/l/72 hours
12.2 Mobility: The dissipation of azides in soil is not by microbial action but is strictly a chemical process accelerated by increasing acidity and elevated temperatures.
12.3 Persistency and degradability: not available
12.4 Bioaccumulation potential: not available
12.5 Evaluation PBT result: not available
12.6 Other toxic effects: not available

SECTION 13 Disposal considerations

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws

SECTION 14 Transport information

Not classified for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

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

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Replaces: New issue
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