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

1.1 Product identifier

- Product Name: CREATINE KINASE (CK-MB)

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

The sets are designed for Health Service laboratories for determination of creatincinase concentration in serum and plasma.The mixture is intended for professional 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 Classification of the substance or mixture:

None

2.2 Label elements:

None

2.3 Other hazards:

None

SECTION 3 Composition/information on ingredients

3.1 Substances and/or Mixtures

All concentrations of potentially hazardous substances or mixtures are below the specific concentration limits and M-factors for hazardous identification. As preparations, the product components are not classified as hazardous. The following substance exceeds the generic cut-off value and is listed with its concentration level. At this concentration level, the substance is not hazardous. See section 16 for definitions for all risk and hazards classifications.

3.1.1 CK-MB Calibrators

N/A

3.1.2 CK-MB Enzyme Reagent

N/A

3.1.3 Streptavidin Coated Plate

N/A

3.1.4 Substrate A

N/A

3.1.5 Substrate B

N/A

3.1.6 Wash Solution Concentrate

N/A

3.1.7 Stop Solution

Chemical Name	Identification	Hazard Code Risk Phrase	Hazard Class Category Code	Hazard Statement	Concentration
Hydrochloric Acid	CAS:- EC: 231-595-7	C; R34 Xi; R37	Skin Corr. 1B STOT SE 3	H314 H335	< 5%

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.

- 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

SECTION 4 First aid measures (continued…)

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

5.1 Extinguishing media

Carbon dioxide, dry powder, foam, water

5.2 Special hazards arising from the substance or mixture

None

5.3 Advice for firefighters

Wear appropriate personal protective equipment and clothing. Wear selfcontained breathing apparatus, If necessary.

SECTION 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear rubber gloves, impermeable shoe covers and long laboratory coat.

6.2 Environmental precautions

Avoid penetration into sewerage systems, surface and ground water. Avoid soil pollution.

6.3 Methods and material for containment and cleaning up

Cover with suitable absorbing material. After removing the substance, rinse the spot of spilling thoroughly with water and soap. Dispose of waste according to all federal, state, and local regulations.

6.4 Reference to other sections

See Section 8 for personal protective equipment. See Section 13 for appropriate disposal methods.

SECTION 7 Handling and storage

7.1 Precaution for safe handling

Avoid spills. Avoid contact with skin, eyes and clothing. Use suitable protective means to work with the substance. Use in a well-ventilated area. Follow good manufacturing practices when using product. Do not drink, smoke, or eat in work areas.

7.2 Conditions for safe storage, including any incompatibilities

Kit and unopened components:

Store at temperatures between + 2 and + 8 °C in a dry and dark place until expiration date.

Opened components:

Opened reagents are stable for sixty (60) days when stored at 2-8 °C.

For prepared reagents (see product insert):

Diluted wash buffer should be stored at room temperature (2-30°C) for up to 60 days. Working substrate solution should be stored at 2-8 °C and is stable for one (1) year.

7.3 Specific end uses

Product procedure should be performed by a skilled individual or trained professional for in vitro diagnostic use only.

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 Information on basic physical and chemical properties

Physical state (at 20 °C): Microtiter strips are solid; Calibrators, Enzyme Reagent, Wash Solution Concentrate, Substrate Solutions and Stop Solution are liquid.

Colour: Calibrators are straw; Enzyme Reagent is green; Stop solution, Substrates and Wash solution concentrate are clear.

Odour: Odourless

Odour threshold: Not applicable

pH value: Stop solution: < 3; Others: 6.8-7.4

Melting point/freezing point: Not determined

Initial boiling point boiling range: Not determined

Flash point: Not applicable

Evaporation rate: Not determined

Flammability (solid, gas): Not flammable

Upper/lower flammability or explosive limits: Not applicable

Vapour pressure: Not determined

Vapour density: Not determined
Relative density: Not determined
Solubility: Water soluble
Partition coefficient: n-octanol/water: Not determined
Auto-ignition temperature: Not applicable
Decomposition temperature: Not determined
Viscosity: Not determined
Explosive properties: None
Oxidising properties: Not determined

9.2 Other Information
None

SECTION 10 Stability and reactivity

10.1 Reactivity: No known reactivity hazards associated with product
10.2 Chemical Stability: Stable under recommended storage conditions
10.3 Possibility of hazardous reactions: No hazardous polymerization
10.4 Conditions to avoid: Excessive heat and light
10.5 Incompatible materials: Acids
10.6 Hazardous decomposition products: Not determined

SECTION 11 Toxicological information

11.1 Acute toxicity: Not determined
11.2 Skin corrosion/ irritation: Not determined
11.3 Serious eye damage/ irritation: Not determined
11.4 Respiratory or skin sensitisation: Not determined
11.5 Germ cell mutagenicity: Not determined
11.6 Carcinogenicity: No component of this product present at levels > 0.1% is identified as probable, possible or confirmed human carcinogen by NTP (National Toxicology Program), IARC (International Agency for Research on Cancer), or OSHA (Occupational Safety & Health Administration)
11.7 Reproductive toxicity: Not determined
11.8 STOT-single exposure: Not determined
11.9 STOT-repeated exposure: Not determined
11.10 Aspiration hazard: Not determined
11.11 Information on likely routes of exposure: If ingested: No known health effects If inhaled: No known health effects If contact with skin: No known health effects If contact with eyes: No known health effects
11.12 Symptoms related to the physical, chemical, and toxicological characteristics: None after short or long-term exposure

SECTION 12 Ecological information

12.1 Toxicity: Not determined.
12.2 Persistence and degradability: Not determined
12.3 Bioaccumulative potential: Not determined
12.4 Mobility in soil: Not determined
12.5 Results of PBT and vPvB assessment: Not determined
12.6 Other adverse affects: Not determined

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

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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