ARENA BioScien

Safety Data Sheet

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

1.1 Product identifier

- Product Name: **RPR Carbon Antigen**

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

Screening test for Syphilis.

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:

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

1. RPR: Suspension of carbon particles coated with a mixture of lipid antigens in a buffered solution. Contains less than 0.1% of sodium azide as a preservative.
2. Positive Control: Diluted human sera or defibrinated plasma, 0.2 µm filtered. Contains less than 0.1% of sodium azide as a preservative
3. Negative Control: Diluted human sera or defibrinated plasma, 0.2 µm filtered. Contains less than 0.1% of sodium azide as a preservative

SECTION 4 First aid measures

Sodium Azide:

Spill: Not applicable.

Exposure Controls: Not applicable.

Personal Protection: Not applicable.

Physical Properties: Not applicable.

Stability/Reactivity: Stable. Non-reactive in this test.

Toxicological Information: Exposure above acceptable limits may be harmful.

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

Information 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.

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

General Information

Besides other antibodies, Treponema Pallidium produces non-Treponemal antibodies (reagin) in syphilitic persons. These antibodies can be detected by RPR antigen. ATLAS RPR card test is a macroscopic screening test for the qualitative and quantitative detection of reagin antibodies in serum or plasma. The kit contains RPR antigen which is based on the easy to use VDRL carbon antigens. In the presence of the reagin, the antigen causes flocculation of the carbon particles, which appears as black clumps. The charcoal particles contained in the antigen suspension enhances the visual appearance of the coagglutination in positive samples

Colour: Carbon RPR Antigen and Straw controls.

Odor: Odorless.

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard

SECTION 10 Stability and reactivity

Stability:
The product is stable in accordance with the recommended storage conditions.
Materials to be avoided:
None.
Hazardous reactions: No dangerous reactions known.
Hazardous decomposition products:
No dangerous decomposition products known.

SECTION 11 Toxicological information

Acute toxicity:
Quantitative data on the toxic effects of this product is not available.
Primary effects:
After skin contact: No irritating effects known.
After eye contact: No irritating effects known.
Sensitization: No sensitizing effects known.

SECTION 12 Ecological information

Environmental Toxicity:
Quantitative data on the toxic effects of this product is not available.
Persistence and Degradability:
The test kit contains plastic and other components that are not readily degradable.
Incorrect sample and used kit disposable:
Bio-hazards may exert cumulative environmental effects due to chemicals and biological materials present in the test kit.

SECTION 13 Disposal considerations

Product:
Chemical 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 country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent.
or
Remains of samples, reagents and controls should be collected in a recipient for this purpose and autoclaved 1 hour at 121°C.
Packaging:
Disposal must be made in accordance with local waste management regulations.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

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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