



## MATERIAL SAFETY DATA SHEET

### Section 1: IDENTIFICATION

Name: Syphilis Device

Description: Device For Detection Of Syphilis - Serum

Manufacturer: **AMS U.K Ltd.,  
Ballymena Business Centre  
Galgorm, Co.Antrim, BT42 1FL  
+44(0)28 25656868**

Cat No. : RADSYP1

### Section 2: CHEMICAL COMPOSITION

All components contain preparations and are therefore not listed in CAS

| COMPONENT   | CAS No.                                          | DESCRIPTION                                                                                                                                                                  |
|-------------|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Test Device | 20 test devices, individually sealed in pouches. | This product comprises a mixture of components in an <i>in vitro</i> diagnostic medical device. Each test device is impregnated with dry chemicals and biochemical reagents. |
| Tris        | 77-86-1                                          | 0.5 – 1%                                                                                                                                                                     |
| Tween 20    | 9005-64-5                                        | 0.5 – 1%                                                                                                                                                                     |

### Section 3: HAZARDS IDENTIFICATION

|                                  |      |
|----------------------------------|------|
| Hazardous components             | None |
| Physical Hazards                 | None |
| Potential Health Effects Summary | None |
| Product Hazard Classifications   | None |

### Section 4: FIRST AID MEASURES

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the device.

|                    |                |
|--------------------|----------------|
| After skin contact | Not Applicable |
| After eye contact  | Not Applicable |
| After ingestion    | Not Applicable |

### Section 5: FIRE FIGHTING MEASURES

|                                       |                |
|---------------------------------------|----------------|
| Flash Point:                          | Not Applicable |
| Flammable Limits:                     | Not Applicable |
| Autoignition Temperature:             | Not Applicable |
| Extinguisher Media:                   | Not Applicable |
| Special Fire and Explosion Hazards:   | Not Applicable |
| Hazardous Combustion Products:        | Not Applicable |
| Protective Equipment for Firefighter: | Not Applicable |



## **Section 6: ACCIDENTAL RELEASE MEASURES**

|                             |                |
|-----------------------------|----------------|
| Personal safety precautions | Not Applicable |
| Spill and leak procedures   | Not Applicable |
| Environmental precautions   | Not Applicable |

## **Section 7: HANDLING AND STORAGE**

|                                                 |                   |
|-------------------------------------------------|-------------------|
| Precautions to be taken in handling and storage | Not Applicable    |
| Requirements to be met by storage conditions    | Store at 2 – 30°C |
| Other precautions/Special Hazards               | Not Applicable    |

## **Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

|                                             |                                                                      |
|---------------------------------------------|----------------------------------------------------------------------|
| Exposure Limits<br>US OSHA, ACGIH, DFG MAK: | Not Applicable                                                       |
| Personal protective equipment               | Chemical resistant gloves, safety glasses, other protective clothing |
| Engineering controls:                       | Not Applicable                                                       |
| Skin Protection:                            | Not Applicable                                                       |

## **Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

|                             |                                                  |
|-----------------------------|--------------------------------------------------|
| Physical State              | Solid                                            |
| Appearance                  | Laminated test device                            |
| Odour                       | Odourless                                        |
| Flash Point                 | Not Applicable                                   |
| Self-ignition               | The product is not self-igniting                 |
| Danger of explosion         | The product does not present an explosion hazard |
| Melting Point/Boiling Point | Not Applicable / Not Applicable                  |
| Vapour Pressure             | Not Applicable                                   |
| Density (20 °C)             | Not Applicable                                   |
| pH value at 20 °C           | Not Applicable                                   |
| Solubility in water         | Not soluble                                      |

## **Section 10: STABILITY AND REACTIVITY**

|                                  |                                                                                     |
|----------------------------------|-------------------------------------------------------------------------------------|
| Stability                        | Stable under conditions of use until the expiration date on the corresponding label |
| Hazardous Decomposition Products | None known                                                                          |



#### **Section 11: TOXICOLOGICAL INFORMATION**

|                                         |                |
|-----------------------------------------|----------------|
| Toxicity data for hazardous ingredients | Not Applicable |
| Primary routes of exposure              | Not Applicable |
| Potential effects of acute exposure     | Not Applicable |
| Potential effects of chronic exposure   | Not Applicable |
| Symptoms of exposure                    | Not Applicable |
| Chronic Toxicity / Carcinogenicity      | Not Applicable |
| Other effects                           | Not Applicable |

#### **Section 12: ECOLOGICAL INFORMATION**

|                           |                |
|---------------------------|----------------|
| Environmental precautions | Not Applicable |
|---------------------------|----------------|

#### **Section 13: DISPOSAL CONSIDERATIONS**

|                      |                                                                                                                                                                                                                                                                                                                                |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General requirements | 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. |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### **Section 14: TRANSPORT INFORMATION**

The product is not affected by the current rules for transport of hazardous goods (GGVS/ADR, GGVE/RID, IMDG, IATA/ICAO).

#### **Section 15: REGULATORY INFORMATION**

The product is not classified as a dangerous preparation according to 1999/45/EC and 67/548/EEC and 2001/58/EC.

#### **Section 16: OTHER INFORMATION**

The above mentioned information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. AMS UK Ltd shall not be held liable for any damage resulting from handling or from contact with the above product.