

## SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND COMPANY

1.1 Product Name : SYPHILIS HEALTH CHECK CONTROL SET

1.2 Intended use : Controls for SYPHILIS HEALTH CHECK rapid Test (in vitro diagnostic use)

1.3 Information on company issuing the SDS

**VEDALAB**

**Rue de l'Expansion – ZAT du Londeau BP 181 Cerisé 61006 Alençon Cedex (FRANCE)**

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## SECTION 2: IDENTIFICATION OF HAZARDS

2.1 Classification of the substance/mixture

Product was classified on the basis of information from the CE regulation n° 1272/2008, annex I part 2, 3 and 4.

The product is not classified according to regulation 1272/2008

2.2 Labeling elements (1272/2008 (CLP) regulation)

Pictogram: -

Warning information: -

Hazard information: EUH032 (contains sodium azide in diluent)

2.3 Other hazards

Contains bovine albumin

### SECTION 3 : COMPONENTS DESCRIPTION

3.1 Substance ☐ Mixture ☒

#### 3.2 Mixture

##### Hazardous components

| Description                               | Concentration | Classification |
|-------------------------------------------|---------------|----------------|
| 1. Glass vial                             | NA            | Not hazardous  |
| 2. Human serum (positive control only) ** | SQF           | Not hazardous  |
| 3. Sodium Azide*                          | <0.1% (W/V)   | Not hazardous  |
| 4. Bovine albumin                         | <10% (W/V)    | Not hazardous* |

##### Hazards Identification

None. Sodium azide concentration is lower than limits specified in Annex I table 1.1.

\*\* Serum tested and found negative for anti-HCV antibodies, HIV 1&2 & and HBsAg antigen.

\* The albumin is obtained from bovine plasma of French origin and slaughterhouse registered upon French veterinary authorities.

### SECTION 4: FIRST AID

#### 4.1 Description

After inhalation: NA

After contact with skin: Wash with plenty of water

After contact with eyes: Rinse with tap water

After ingestion: NA

#### 4.2 Major signs and effects

NA

#### 4.3 Recommendations for immediate care and specific treatments

NA

### SECTION 5: DISPOSITIONS AGAINST FIRE

5.1 Extinguishing procedures: NA

5.2 Special hazards: NA

5.3 Special wear against fire : NA

## SECTION 6: DISPOSITIONS AFTER ACCIDENTAL SPILLING

NA

## SECTION 7: HANDLING AND STORAGE

7.1 Handling : Normal ☒ With precaution ☐

7.2 Storage : +2°C to +8° C ☒ Room temperature (< 30°C) ☐

## SECTION 8 : RECOMMENDATIONS FOR EXPOSURE /PERSONAL PROTECTION

8.1 Protective respiratory mask : YES ☐ NO ☒

8.2 Protective eyes glasses: YES ☐ NO ☒

8.3 Gloves : YES ☐ NO ☒

8.4 Lab coat : YES ☒ NO ☐

## SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES (LIQUID COMPONENTS ONLY)

9.1 Aspect : Transparent

9.2 Color : Colourless liquid

9.3 Odor : Odorless

9.4 pH- at 20° C : NA

9.5 Boiling point : NA

9.6 Inflammability : NA

9.7 Explosive limits : NA

9.8 Density : Close to 1.0

## SECTION 10 : STABILITY AND REACTIVITY

10.1 Stability: Stable

10.2 Hazardous products from decomposition : NA

10.3 Hazardous polymerisation : NA

## SECTION 11 : TOXICOLOGIC INFORMATION

Not toxic

## SECTION 12 : ECOLOGIC INFORMATION

12.1 Toxicity: Azide only (In case of appropriate handling ecological problems are not expected)

Fish : Acute 1

Algae : NA

Bacteria : NA

Daphnia : NA

12.2 Persistence and Degradability

NA

12.3 Bioaccumulation

NA

### SECTION 13 : RECOMMENDATIONS FOR DISPOSAL

Disposal in accordance with local regulations.

### SECTION 14 : RECOMMENDATIONS FOR SHIPMENT

14.1 ADR/RID/AND: NA

14.2 IMDG: NA

14.3 ICAO-TI/IATA: NA

14.4 Other information:

### SECTION 15 : LEGAL INFORMATION

Labeling in conformance with EU directives: Conforms

☒ As far as we know, this product contains no substances listed in Annex XIV of R.E.A.C.H. regulation.

☐ This product contains substances submitted to authorisation as required in R.E.A.C.H. regulation.

### SECTION 16 : OTHER INFORMATION

Information from this sheet has been prepared from the available product data on the basis of the more reliable information. However this information cannot be considered as exhaustive but rather as guidelines. VEDALAB company cannot be considered responsible for any damage resulting from use or contact with the product.

| Signed by :           | Position :               | Date :                          |
|-----------------------|--------------------------|---------------------------------|
| Raphaël DONATI (Ph D) | C.E.O/Technical Director | October 08 <sup>th</sup> , 2018 |

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