

# MATERIAL SAFETY DATA SHEET

## 1) IDENTIFICATION OF PRODUCT AND SUPPLIER

- **Product Name :** SEROLOGY (120)  
Ref: 00097
- **Product use:** In Vitro Diagnostic Medical Device for purpose of medical analysis
- **Supplier :** ELITech MICROBIO  
19 allées d'Athènes  
Parc d'activité  
83870 SIGNES  
FRANCE  
Tel: 33 (0)4.94.88.55.00  
Fax: 33 (0)4 94 88.55.22  
Email : elitechmicrobio.msds@elitechgroup.com
- **Appel d'urgence :** Contact the nearest poison center.

## 2) HAZARDS IDENTIFICATION

- **Main hazard :** This preparation is classified as non hazardous according the directive 1999/45/EEC  
The preparation contain biological agents
- **Effect of acute exposure**
  - . Skin contact : May be harmful if absorbed through the skin. May be irritating
  - . Eye Contact : May be irritating
  - . Inhalation: May be harmful if inhaled. Material may be irritating to respiratory system.
  - . Ingestion: May be harmful if swallowed.
  - . Infectious : Urogenital mycoplasma
- **Pour l'environnement :** The preparation contain antimicrobial agents. These should not be discarded in the environment to prevent a development of microorganism resistance.
- **After reconstitution :** The reagents, after reconstitution, are potentially infectious and must be handled with caution, in observance of hygiene rules and the current regulations for this type of product in the country of use.
- **Classification:** no dangerous according to the 1999/45/ECC directive
- **Risks and security :** R 36/37/38 ; S22;S26;S36;S46

## 3) COMPOSITION / INFORMATION OF INGREDIENTS

This product contain :

- 120 lyophilized SEROLOGY U.u/M.h – ref 1119
- 120 vials of liquid medium UMMt (2ml) – ref 1126
- 120 lyophilized UMMIyo (+ 2ml UMMt) – ref 1128
- 120 trays SEROLOGY – ref 1120
- 5 lyophilized SEROLOGY CONTROL (+) – ref 1121

### \* SEROLOGY U.u/M.h – ref 1119

Substance	No.-CAS	N° CE	Classification	Concentration
Chlorure de sodium	7647-14-5		Xi, R36/37/38	< 1.5 %
Souches U.u (Ureaplasma urealyticum)	-	-	Classe 1 (selon classification OMS)	
Souches M.h (Mycoplasma hominis)	-	-	Classe 2 (selon classification OMS)	

### \* UMMIyo (+ 2mL UMMt) – Ref 1128

Substance	No.-CAS	N° CE	Classification	Concentration
(+)-L-Arginine hydrochloride	214-275-1		Xi ; R36/38	< 4%

## \* SEROLOGY – ref 1120

Substance	No.-CAS	N° CE	Classification	Concentration
Phenol Red sodium salt	34487-61-1		Xi ; R36/38/38	< 6%

## \* SEROLOGY CONTROL (+) – ref 1121

Substance	No.-CAS	N° CE	Classification	Concentration
Chlorure de sodium	7647-14-5		Xi, R36/37/38	< 5 %

**4) FIRST AID MEASURES**

**General advice:** Consult a physician. Show this safety data sheet to the doctor in attendance.

- **Eyes contact :** Flush eyes with plenty of water . Seek medical advice.
- **Skin contact :** Flush area with soap and plenty of water and with a disinfectant.
- **Inhalation :** Remove to fresh air. If not breathing, give artificial respiration. Call a physician.
- **Ingestion:** Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Seek medical advice..
- **Infection :** Consult a physician

**5) FIRE-FIGHTING MEASURES**

- **Extinguishing media :** Use extinguishing measures that are appropriate to local circumstances and surrounding environment..
- **Special risks :** If devices are stored in large quantity :Mask for respiratory and eye protection ; special protective equipment and gloves for skin protection..
- **Infectious hazards :** Inform help about localization and cautions to be taken.

**6) ACCIDENTAL RELEASE MEASURES**

- **Individual protection:** Gloves, Mask, Lab coat
- **Measure for environmental protection:** Do not let product enter drains, surface and ground water. Limit the spreading by using absorbent material. Avoid airstream.
- **Measure for cleaning/collecting:** Place in a suitable-closed container, and hold for biological waste disposal. Avoid raising dust. Ventilate area, wash and disinfect spill site after material pickup is complete. Disposal procedures have to be respected (see § 13). .

**7) HANDLING AND STORAGE**

The product are potentially infectious and must be handled with caution, in observance of hygiene rules and the current regulations for this type of product in the country of use

- **Handling :** Usual precautions to prevent vial breakages.  
Open and handle vial with due care. Not breath dust. Wash hands after use.  
The usual precautions taken when handling microbiological products should be observed. Refer to §8
- **Storage :** Store at 2-8°C. Keep tightly closed in a dry and well ventilated area Stocker à 2-8°C.

**8) EXPOSURE CONTROLS/PERSONAL PROTECTION**

- **Engineering controls:** Provide appropriate exhaust ventilation at places where dust is formed to maintain air-born concentrations low. Provide a shower and a eyewash fountain
- **Personal protective equipment:**
  - . Respiratory protection: Not required. Where risk assessment shows air-purifying respirators are appropriate, use a dust mask type N99 (US) or type P2 (EN143) to protect from dusts. Use material tested and approved under appropriate government standards such as NIOSH (US) and CEN (EU).

- . Eye protection: Wear chemical safety goggles.
- . Hand protection: Wear chemical-resistant protective gloves satisfying to Directive EU 89/689/CEE and to deriving standard EN 374.
- . Skin protection: Wear appropriated protective clothes.

- **General hygiene measures:** Wash thoroughly after handling and before break. Wash contaminated clothes before reuse.

## 9) PHYSICAL AND CHEMICAL PROPERTIES

	<b>SEROLOGY Uu/Mh Ref 1119</b>	<b>UMMt (2 mL) Ref 1126</b>	<b>UMMIyo (+2 mL) Ref 1128</b>	<b>SEROLOGY Ref 1120</b>	<b>SEROLOGY CONTROL(+) Ref 1121</b>
<b>Appearance</b> <b>Color</b>	Lyophilized orange	Liquid orange	Lyophilized orange	Solid NA	Lyophilized jaune-orange
<b>Propriétés</b> <b>Melting point</b> <b>pH</b> <b>Boiling point</b> <b>Flash point</b> <b>Ignition temperature</b> <b>Explosion limits</b> <b>Density</b>	Donnée non disponible Donnée non disponible Donnée non disponible Donnée non disponible Donnée non disponible Donnée non disponible Donnée non disponible				
<b>Solubilité dans l'eau</b>	Soluble	Soluble	Soluble	Soluble	Soluble

## 10) STABILITY AND REACTIVITY

- **Stability:** Stable until the expiry date stated on the label.

## 11) TOXICOLOGICAL INFORMATION

- **Route of exposure:** See point 2).
- **Acute toxicity:** no data available
- **Irritation and corrosion:** no data available
- **Sensitization:** no data available
- **Chronic exposure:** no data available
- **Signs and symptoms of exposure:** no data available

## 12) ECOLOGICAL INFORMATION

- No data available for elimination (persistence and degradability) and for ecotoxicity effects.
- Disposal procedures have to be respected (see § 13).

## 13) DISPOSAL CONSIDERATIONS

- **Wastes evacuation procedure:** Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state, and local environmental regulations.
- **Contaminated packaging:** Dispose of as unused product.

## 14) TRANSPORT INFORMATION

**ADR :** unregulated according  
**IMDG :** unregulated according  
**IATA :** unregulated according

## 15) REGULATORY INFORMATION

**Device registered according to :** 98/79/EC directive (in vitro diagnostic medical devices)

**Classification and labelling according to** 1999/45/EC directive

**Hazard symbol** : Biohazard class 2 according OMS classification

## 16) OTHER INFORMATION

The material safety data sheet is established according to the Regulation (EC) n° 1907/2006.

- Risk sentences, §3 : R36/38/38 : Irritating to eyes, respiratory system and skin
- Safety sentences; § 3 : S22 : Do not breathe dust
- S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
- S36 : Wear suitable protective clothing
- S46 : If swallowed, seek medical advice immediately and show this container or label

**The reagents in this kit are intended solely for in vitro use and must be handled by authorized personnel**

The information herein is based on the current extent of our knowledge and is believed to be correct but is provided without warranty of any kind. The recipient of our product is responsible for observing all applicable laws and regulations