



# SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Doc. N° UC80502 SSE rev.2  
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## 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 Product identifiers

Product number: **UC80502**  
Product name: **TPHA TEST - CONTROLS**

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

Identified uses **Positive and negative controls, ready to use, for Cod. UC80500, UC80501 and UC80515**

### 1.3 Details of the supplier of the safety data sheet

Company **Mascia Brunelli S.p.A.**  
Viale Monza 272, 20128 Milano, Italy.  
Tel.: 0039 02 25209.1  
Fax: 0039 02 2576428  
E-mail: [mktg@masciabrunelli.it](mailto:mktg@masciabrunelli.it)

### 1.4 Emergency telephone number

Emergency Phone **0039 02 66101029 (Centro Antiveleni Niguarda Ca' Granda – Milano)**

## 2 – HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008  
This substance is not classified as dangerous according to EC Directives 67/548/EEC or 199/45/EC

### 2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

### 2.3 Other hazards – none

## 3 – COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2 Mixtures

Negative control: saline solution with biological additives and bacteriostatics agents.  
0.05% sodium azide as preservative  
Positive Control: stabilized liquid control, reactive with erythrocytes test cells

For Positive Control: Components from human origin have been tested and found negative for the presence of HBsAg, HCV and antibody to HIV (1/2). However handle cautiously as potentially infectious

## 4- FIRST AID MEASURES

### 4.1 Description of first aid measures

#### If inhaled

Inhalation of any component in this kit is unlikely. If a component is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.

#### If swallowed

Ingestion of small amounts of the components of the kits should not be toxic, however, a physician should be immediately.

#### In case of eye contact

In case of contact with the components of the kit, immediately flush eyes with plenty of water.

#### In case of skin contact

The components of the kit are not likely to be hazardous by skin contact. However in case of contact, immediately clean skin with plenty of water and soap.



**4.2 Most important symptoms and effects, both acute and delayed**

no data available

**4.3 Indication of any immediate medical attention and special treatment needed**

no data available

**5 - FIRE-FIGHTING MEASURES**

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**5.1 Extinguishing media**

For small fires, use water or CO<sub>2</sub>.

**5.2 Special hazards arising from the substance or mixture**

no data available

**5.3 Advice for firefighters**

This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel.

**6- ACCIDENTAL RELEASE MEASURES**

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**6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment, lab coat and gloves

**6.2 Environmental precautions**

Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment

**6.3 Methods and material for containment and cleaning up**

Use adsorbent paper towel or cloth to adsorb the spill solution and dispose or clean the contaminated surface in accordance with local procedures or appropriate standards.

**6.4 Reference to other sections**

For disposal see section 13.

**7 – HANDLING AND STORAGE**

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**7.1 Precautions for safe handling**

Don't eat, drink, smoke in laboratory area. Use the product according to the product insert.

**7.2 Conditions for safe storage, including any incompatibilities**

Keep product at 2-8 °C. Do not freeze. Keep away from children.

**7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

**8- EXPOSURE CONTROLS - PERSONAL PROTECTION**

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**8.1 Control parameters**

Any specific protection and prevention measures should not be taken during use of the product.

**Components with workplace control parameters**

No information available

**8.2 Exposure controls**

The positive control and all the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

**Personal protective equipment**

**Eye/face protection**

Use safety glasses.

**Skin protection**

Handle with gloves. Use with a lab coat.

**Body Protection**

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection**

Respiratory protection is not required.

**9 – PHYSICAL AND CHEMICAL PROPERTIES**

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**9.1 Information on basic physical and chemical properties**

a) ) Appearance Form	Negative Control transparent liquid colorless	Positive Control transparent liquid yellowish
b) Odour	odourless	odourless
c) Odour Threshold	no data available	



d) pH	no data available
e) Melting point/freezing point	no data available
f) Initial boiling point and boiling range	no data available
g) Flash point	no data available
h) Evaporation rate	no data available
i) Vapour pressure	no data available
j) Vapour density	no data available
k) Relative density	no data available
l) Water solubility	no data available
m) Viscosity	no data available
n) Explosive properties	no data available
o) Oxidizing properties	no data available

**9.2 Other safety information** no data available

## 10 – STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	No known hazardous reactivity
<b>10.2 Chemical stability</b>	Stable under recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	no data available
<b>10.4 Conditions to avoid</b>	no data available.
<b>10.5 Incompatible materials</b>	no data available.
<b>10.6 Hazardous decomposition products</b>	no known hazardous decomposition products

## 11 – TOXICOLOGICAL INFORMATION

<b>11.1 Information on toxicological effects</b>	
<b>Acute toxicity</b>	Product does not present an acute toxicity hazard based on known or supplied information
<b>Skin corrosion/irritation</b>	No data available.
<b>Serious eye damage/irritation</b>	No data available.
<b>Respiratory or skin sensitisation</b>	No data available.
<b>Germ cell mutagenicity</b>	No data available.
<b>Carcinogenicity</b>	No data available.
<b>Reproductive toxicity</b>	No data available.
<b>Summary of evaluation of the CMR properties</b>	No data available.
<b>STOT-single exposure</b>	No data available.
<b>STOT-repeated exposure</b>	No data available.
<b>Aspiration hazard</b>	No data available

## 12 – ECOLOGICAL INFORMATION

<b>12.1 Toxicity</b>	no data available
<b>12.2 Persistence and degradability</b>	no data available
<b>12.3 Bio accumulative potential</b>	no data available
<b>12.4 Mobility in soil</b>	no data available
<b>12.5 Results of PBT and vPvB assessment</b>	no data available
<b>12.6 Other adverse effects</b>	no data available

## 13 – DISPOSAL CONSIDERATIONS

<b>13.1 Waste treatment methods</b>	
<b>Product</b>	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
<b>Contaminated packaging</b>	Do not remove labels from containers for disposal or recycling. Observe all the attention and precautions listed for the product.

## 14 – TRANSPORT INFORMATION

The product is considered non dangerous for transportation	
<b>14.1 UN number</b>	ADR/RID: - IMDG: - IATA: -
<b>14.2 UN proper shipping name</b>	ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods



<b>14.3 Transport hazard class(es)</b>	ADR/RID: - IMDG: - IATA: -
<b>14.4 Packaging group</b>	ADR/RID: - IMDG: - IATA: -
<b>14.5 Environmental hazards</b>	ADR/RID: no IMDG Marine pollutant: no IATA: no
<b>14.6 Special precautions for user</b>	no data available

## **15 – REGULATORY INFORMATION**

### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for in vitro diagnosis, so they must meet the criteria described in Directive 98/79/CE

**15.2 Chemical Safety Assessment** no data available

## **16 – OTHER INFORMATION**

The information in this MSDS was obtained from current and reliable sources. Anyone using this information is solely responsible for the accuracy and applicability of this information to a particular use or situation.

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