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## Safety Data Sheet

### 1.0 IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

- 1.1 Product name: HPV Selfy product line (code: UBM0002 – UBM0013- UBM0020 – UBM0021 – UBM0022 – UBM0023 – UBM0024 – UBM0025)
- 1.2 Identified use: *In vitro* diagnostics.  
Identification and quantification with gene amplification techniques.
- 1.3 Details of the supplier: Ulisse Biomed S.p.A.  
Legal site: via Cavour 20, 33100 Udine – ITALIA  
Operative site: Area Science Park, SS 14, km 163.5, 34149 Trieste - ITALIA  
Phone. +39.0403757530  
Fax. +39. 0403757542
- 1.4 Emergency telephone number: 112

### 2.0 HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:  
SLV0005 contains Syto 9 Green, tetramethylammonium chloride, and DTT (refer to the MSDS of the Level I Semi-finished products).  
**Classification according to Regulation (EC) No 1272/2008:**  
Refer to Hazard and Precautionary Statements in this document, page 2. For other specific indications of danger, see the MSDS of the raw materials.

**Specific hazards indications for humans and for the environment:**  
H302, H402, H301+H311, H370, H315, H411

#### 2.2 Label elements:

Labelling according to Regulation (CE) No 1272/2008:

##### Pictograms:

None in the external package.

Only on the tube of SLV0005 given the limited amounts.



**Warning:**  
Attention

**Hazard statements:**

H302 Harmful if swallowed  
H412 Harmful to aquatic life with long-lasting effects.  
H301+H311: Toxic if swallowed or in contact with skin.  
H370: Causes damage to organs.  
H315: Causes skin irritation.  
H411: Toxic to aquatic life with long-lasting effects.

**Precautionary statements:****Prevention**

P273 Avoid release to the environment.  
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

**Disposal**

P501 Dispose of contents/container in accordance with local/national regulation.

**3.0 COMPOSITION/INFORMATION ON INGREDIENTS**

- **Chemical characteristics:**  
Composition of 8 different and separate mixtures (I level semi-finished products)
- **Description:**  
See PP20.

**Dangerous substances:**

Component	CAS number	Wt %
Syto 9 Green (NONE (0.1-1)	NONE	<1
tetramethylammonium chloride	75-57-0	<1
Ditio-threitol	3483-12-3	<1

**FIRST AID MEASURES**

- **Immediately consult a physician in case of exposure:**  
Show this safety data sheet to the doctor in attendance
- **If inhaled:**  
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
- **In case of skin contact:**  
Wash with soap and plenty of water. Consult a physician.
- **In case of eye contact:**  
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
- **If swallowed:**  
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

**4.0 FIREFIGHTING MEASURES****In case of fire:**

- **Suitable extinguishing media:**  
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
- **Extinguished media NOT to be used for safety reasons:**  
No fire fighting media in particular
- **Special hazards arising from the substance or mixture:**  
The nature of the decomposition products is unknown.
- **Advice for firefighters:**  
Wear self-contained breathing apparatus for firefighters if necessary.

## 6.0 **ACCIDENTAL RELEASE MEASURED** (if necessary, see sections 8, 13)

- **Personal precautions:**  
Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.
- **Environmental precautions:**  
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.
- **Methods and materials for containment and cleaning up:**  
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

## 7.0 **HANDLING AND STORAGE**

### 7.1 **Handling**

**Precautions for safe handling:** Avoid contact with skin and eyes. Avoid formation of dust and aerosol. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section **Conditions/materials to avoid:** Undefined.

### 7.2 **Storage**

- **Coonditions for safe storage:** Store in cool place. Keep the container in a dry and well-ventilated place. Moisture sensitive.
- **Prevention of the accumulation of electrostatic charges:** no special measures are required.
- **Quantitative limits in storage conditions:** None.

### 7.3 **Specific end use(s):** no other specif uses are stipulated

## 8.0 **EXPOSURE CONTROLS/ PERSONAL PROTECTION**

### 8.1 **Limit values for exposure in the workplace**

- **Components with limit values that require monitoring at the workplace (see section 3):** None.

### 8.2 **Exposure controls**

#### **Appropriate engineering controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### **Eye/face protection**

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

#### **Skin protection:**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374 If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

**Body protection:**

Impervious clothing, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace

**Respiratory protection:**

Where risk assessment shows air-purifying respirators are appropriate use a fullface particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

- **Control of environmental exposure:**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

**9.0 PHYSICAL AND CHEMICAL PROPERTIES****9.1 General information – Appearance:**

**Physical state at 25°C:**

**Color:** colorless

**Form:** Liquid

**Odor:** No data available

**9.2 Other safety information:**

**pH:** No data available

**Initial boiling point and boiling range:** No data available

**Flammability(liquids):** Not Applicable

**Flammability (solid):** Applicable

**Flammability (gas):** Not Applicable

**Explosive properties:** No data available

**Vapor pressure:** Undefined

**Relative density:** Undefined

**Water solubility:** Soluble

**Viscosity:** Undefined

**Vapor density (air=1):** No data available

**Evaporation rate:** No data available

**10.0 STABILITY AND REACTIVITY****10.1 Reactivity**

No data available

**10.2 Chemical stability**

Stable under recommended storage conditions.

**10.3 Possibility of hazardous reactions**

No data available

**10.4 Conditions to avoid**

Avoid moisture.

**10.5 Incompatible material**

Strong oxidizing agents, Strong acids, Strong bases, Strong reducing agents

**10.6 Hazardous decomposition products**

Other decomposition products - No data available

In the event of fire: see section 5

#### 11.0 TOXICOLOGICAL INFORMATION

- **Information on toxicological effects:**
- **Acute toxicity:** No data available
- **Skin corrosion/irritation**  
No data available
- **Serious eye damage/eye irritation**  
No data available
- **Respiratory or skin sensitization**  
No data available
- **Germ cell mutagenicity**  
No data available
- **Carcinogenicity**  
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by IARC.
- **Reproductive toxicity**  
No data available
- **Specific target organ toxicity - single exposure**  
No data available
- **Specific target organ toxicity - repeated exposure**  
No data available
- **Aspiration hazard**  
No data available
- **Additional Information**  
RTECS: EK1610000  
Nausea, Headache, Vomiting, Central nervous system depression, To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.  
Liver - Irregularity - Evaluated on the basis of human scientific evidence

#### 12.0 ECOLOGICAL INFORMATION (IF NECESSARY, SEE SECTIONS 6, 7, 13, 14 e 15)

- **Toxicity:**
  - **Aquatic toxicity:**  
Toxicity to fish CE50 – Daphnia magna (large water flea) - 27 mg/l – 48 h
- **Persistence and degradability**  
No data available
- **Bioaccumulative potential**  
No data available
- **Mobility in soil**  
No data available
- **Results of PBT and vPvB assessment**  
**PBT:** No data available  
  
**vPvB:** No data available
  - **Other adverse effects** No data available

#### 13.0 DISPOSAL CONSIDERATION

- **Safety measures and procedures for handling waste and product residues:** Deliver non-recyclable solutions and surpluses to an authorized waste disposal company. Solubilize or mix the product with a combustible solvent, then burn in an incinerator for chemical products equipped with an afterburning system and a blast chiller.
- **Appropriate disposal measures for contaminated packaging:** Dispose of as unused product.
- **European Community provisions on waste - national or regional legislation in force:**  
There are no uniform CE regulations for the disposal of chemicals and their residues. Chemical residues must be considered as hazardous waste. The disposal of hazardous waste is governed by specific laws and regulations in each member state. In Italy, disposal must comply with Legislative Decree no. 22 of 5 February 1997 and subsequent additions and amendments thereto. Observe all national and local regulations for waste disposal.

#### 14.0 **TRANSPORT INFORMATION**

The product is classified as dangerous goods in accordance with current legislation for the various modes of transport: road (ADR) and air (IATA) (see point 14.6 Table Below)

<b>14.1</b> Number ONU ADR, ADN, IMDG, IATA	ADR/RID: -    IMDG: -    IATA:3335
<b>14.2</b> shipping name ONU ADR, ADN, IMDG, IATA	Not dangerous goods
<b>14.3</b> Transport hazard classes ADR, ADN, IMDG, IATA Classe	ADR/RID: -    IMDG: -    IATA:9
<b>14.4</b> packing group ADR, IMDG, IATA	ADR/RID: -    IMDG: -    IATA: III
<b>14.5</b> Environmental hazards: Marine pollutant:	none
<b>14.6</b> special precautions for users:	No data available
<b>14.7</b> Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable

#### 15.0 **REGULATORY INFORMATION**

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

##### 15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

#### 16.0 **OTHER INFORMATION**

- **Label information**

- **Trading name:** HPV Selfy product line (code: UBM0002 – UBM0013- UBM0020 – UBM0021 – UBM0022 – UBM0023 – UBM0024 – UBM0025)
- **European commercial authorization holder**  
Ulisse Biomed S. p.A.  
Legal site: via Cavour 20, 33100 Udine - ITALIA  
Operative site: Area Science Park, SS 14, km 163.5, 34149 Trieste - ITALIA  
phone. +39.0403757530  
Fax. +39. 0403757542
- **It contains:**  
Chemical name of components: see Sections 3 and 16.
- **Classification and hazard labeling of the product**

The SLV0005 is classified as dangerous according to Regulation (EC) No. 1272/2008.

H302 Harmful if swallowed.

H412 Harmful to aquatic life with long lasting effects.

H301+H311: toxic if swallowed or in contact with skin  
H370: causes damage to organs  
H315: causes skin irritation  
H411: toxic to aquatic fauna with long lasting effects

- **Nominal content of the packaging**  
Approximate volume 5 ml (SLV0005 1.5ml)
- **Sales and use restrictions:**  
for professional use only
- **Exposure limits**  
see section 8.

The information contained in the document is based on our knowledge as of the date stated below and is provided without express or implied guarantee of accuracy. Operators receiving such information should exercise their independent judgment in determining the accuracy, completeness and suitability of the product for a specific use. There is no guarantee that all safety measures have been described in this safety data sheet, and that further measures cannot be required in particular and exceptional situations or conditions. Ulisse Biomed S.p.A. assumes no responsibility deriving from the irresponsible, improper or illegal, direct or indirect, use of the product presented and sold. Do not use the product for purposes other than those for which it is intended. Improper use can cause risks that are not covered in this document.

**Ulisse Biomed S. p. A. remains at your disposal for further information and any clarifications.**