

Ulisse BioMed spa - Via Cavour 20  
33100 Udine - ITALY  
Offices: Phone. +39 040 375 7530 - Fax +39-040 375 7542  
E. mail: [info@ulissebiomed.com](mailto:info@ulissebiomed.com)  
Web site: [www.ulissebiomed.com](http://www.ulissebiomed.com)

## Safety Data Sheet

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

- |     |                             |   |
|-----|-----------------------------|---|
| 1.1 | Product name:               | Ulisse Faster DNA   |
| 1.2 | Product code:               | UBM0014   |
| 1.3 | Identified use:             | preanalytical reagent for <i>In vitro</i> diagnostics.<br>(compatible with SAGITTA-based real time PCR)   |
| 1.4 | Details of the supplier:    | Ulisse Biomed S.p.A.<br><u>Legal site</u> : via Cavour 20, 33100 Udine – ITALIA<br><u>Operative site</u> : Area Science Park, SS 14, km<br>163.5, 34149 Trieste - ITALIA<br>Phone. +39.0403757530<br>Fax. +39. 0403757542 |
| 1.5 | Emergency telephone number: | Centro Antiveleni Istituto Giannina Gaslini<br>010 56 36 245<br>Or National Emergency Number 118  |

## 2.0 HAZARDS IDENTIFICATION

### 2.1 **Classification of the substance or mixture:**

Contains Proteinase K .

#### **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:**

H315, H319, H334, H335

### 2.2 **Label elements:**

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

##### **Pictograms:**



**Warning:** Attention

##### **Hazard statements:**

H315

H319

H334

H335

##### **Precautionary statements:**

###### **Prevention**

P261

P305 + P351 + P338

P342 + P311

###### **Disposal**

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

### 3.0 COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

N/A

#### 3.2 Mixture

Component	CAS No	EC-No	Conc. (%)	Classification according to Regulation CE n.1272/2008 (CLP)
Proteinase K	39450-01-6	254-457-8	<1%	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Resp. Sens. 1; H334 Skin Sens. 1; H317 STOT SE 3; H335

### 4.0 FIRST AID MEASURES

#### 4.1 Description of 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 .

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

It causes skin irritation.  
May cause a skin allergic reaction.  
It causes severe eye irritation.  
It can cause allergic or asthmatic symptoms or breathing difficulties when inhaled.  
It can irritate the airways.

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

Symptomatic treatment: first aid procedure to be defined in accordance with physician.

### 5.0 FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

##### 5.1.1 Suitable extinguishing media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

##### 5.1.2 Extinguished media NOT to be used for safety reasons:

Plenty water-jet.

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

The nature of the decomposition product is not known.

Combustible.

Development of hazardous combustion gases or vapors possible in the event of fire.

### 5.3 Advice for firefighters

Wear self-contained breathing apparatus.

Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

### 5.4 Further Information

Prevent fire extinguish water from contaminating surface water or the ground water system.

## 6.0 ACCIDENTAL RELEASE MEASURED

### 6.1 Personal precautions, protective equipment and emergency procedures:

Advice for non-emergency personnel: avoid dust formation and its inhalation.

Avoid substance contact. Ensure adequate ventilation.

Avoid breathing vapors, mist or gas.

Evacuate the danger area, observe emergency procedures.

Use personal protective equipment. For details related to personal protection see section 8.

### 6.2 Environmental precautions:

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

### 6.3 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.

### 6.4 Reference to other sections: for disposal see section 13.

## 7.0 HANDLING AND STORAGE

### 7.1 Precautions for safe handling:

Avoid contact with skin and eyes. Avoid formation of aerosol. Do not breath vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 8. Avoid exposure. Provide sufficient air exchange and /or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations.

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

Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.

### 7.3 Specific end uses(s):

Laboratory chemicals: no other specified uses are stipulated

## 8.0 EXPOSURE CONTROLS/ PERSONAL PROTECTION

### 8.1 Control parameters:

#### Occupational Exposure Limits

COMPONENTS	CAS-N°	VALUE TYPE (FORM OF EXPOSURE)	CONTROL PARAMETERS	BASIS
Proteinase, Tritirachium album serine	39450-01-6	IOEL	0,00006 MG/M3	Roche Industrial Hygiene Committee (RIHC)

## 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: > 30 min

*Splash contact.*

Material: Nitrile rubber. Minimum layer thickness: 0,11 mm. Break through time: > 30 min

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 full-face 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 Information on basic physical and chemical properties

– **Appearance:**

- **Physical state at 25°C:**
- **Color:** colorless
- **Form:** Liquid
- **Odor:** No data available

### 9.2 Other 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 materials:** Strong oxidizing agents, Strong acids, Strong bases, Strong reducing agents
- 10.6 Hazardous decomposition products:** No data available  
In the event of fire: see section 5

## 11.0 **TOXICOLOGICAL INFORMATION**

- 11.1 Information on toxicological effects:**
- **Acute toxicity:** Not classified based on available information.
  - **Skin corrosion/irritation:** Not classified based on available information.  
**Product:**  
Remarks: may cause skin irritation and/or dermatitis.  
**Components:**  
Proteinase K  
Results: irritating to skin  
Remarks: may cause skin irritation and/or dermatitis
  - **Serious eye damage/eye irritation:** Not classified based on available information.  
**Product**  
Remarks: vapors may cause irritation to the eyes, respiratory system and the skin.  
**Components:**  
Proteinase, Tritirachium album serine:  
Result : Irritating to eyes.  
Remarks : May cause irreversible eye damage
  - **Respiratory or skin sensitization:**  
Skin sensitization  
May cause an allergic skin reaction.  
Respiratory sensitization  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
**Product:**  
Remarks : Causes sensitization.  
**Components:**  
Proteinase, Tritirachium album serine:  
Assessment : May cause sensitization by skin contact.  
Remarks : Causes sensitisation.  
Assessment : May cause sensitisation by inhalation.
  - **Germ cell mutagenicity:** Not classified based on available information.

- **Carcinogenicity:** 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:** Not classified based on data available.
- **Specific target organ toxicity - single exposure:** Not classified based on data available.
- **Specific target organ toxicity - repeated exposure:** Not classified based on data available.
- **Aspiration hazard:** No data available
- **Additional Information:** N.A.

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

### 12.1 **Toxicity:**

**Aquatic toxicity:** . No data available

**Toxicity Data on Soil :** Not expected to adsorb on soil.

**Other organisms relevant to the environment :** No data available

12.2 **Persistence and degradability:** No data available

12.3 **Bioaccumulative potential:** No data available

12.4 **Mobility in soil :** No data available

12.5 **Results of PBT and vPvB assessment:** No data available.

12.6 **Other adverse effects:** No other data available

## 13.0 **DISPOSAL CONSIDERATION**

### 13.1 **Waste treatment methods**

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.

Send to a licensed waste management company.

Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.

Dispose of as unused product.

Empty containers should be taken to an approved waste handling site for recycling or disposal.

Do not re-use empty containers.

#### 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 Class	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.

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

##### **15.2 Chemical safety assessment:**

For this product a chemical safety assessment was not carried out

#### 16.0 **OTHER INFORMATION**

##### **Label information**

- **Trading name:** Ulisse Faster DNA
- **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 - Italy  
phone. +39.0403757530  
Fax. +39. 0403757542
- **It contains:** Chemical name of components: see also Sections 3
- **Classification and hazard labeling of the product:**

##### **Full text of H-Statements**

H315 : Causes skin irritation.

H317 : May cause an allergic skin reaction.

H319 : Causes serious eye irritation.

H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled

H335 : May cause respiratory irritation.

- **Nominal content of the packaging:** 1.5 ml of Buffer P (diluted Proteinase K solution).
- **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.

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