

## Section 1. Identification of the substance / mixture and of the company

### 1.1 Product identifier

Lipase-VET control kit, VT 1800

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

In-vitro diagnostics; please refer to the product insert.

### 1.3 Supplier's details

Company name	Eurolyser Diagnostica GmbH
Address, P.O. Box	Bayernstraße 11a
Postcode / Place	5020 Salzburg
Country	Österreich
Telephone	+43 662 432100
Facsimile	+43 662 432100 50
E-Mail	sds@eurolyser.com

### 1.4 Emergency telephone number

Toxicological information-emergency centre +43 1 406 43 43

MO – SU, 0 – 24 h German and English

## Section 2. Hazards Identification

### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 (CLP)

Mixture not classified as hazardous

### 2.2 Label elements

Mixture	has not to be labelled
Hazard pictograms	not applicable
Signal words	not applicable
Hazard statement(s) in full	not applicable
Precautionary statement(s) in full	not applicable
Any additional hazardous information (EU)	not applicable
Any additional applicable label elements	not applicable

## 2.3 Other hazards

This product contains a substance with human origin.

Hazardous properties cannot be excluded. No dangers expected for the user if used according to directions. Donors have been tested by FDA approved methods, test results turned out negative for antibodies to HIV-1 and HIV-2, non-reactive for HBsAg, and non-reactive for HCV. Even though tests on infectious diseases ended negative, this product should be handled as potentially infectious biomaterial.

Product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

## Section 3. Composition / information on ingredients

### 3.1 Substance

Not applicable.

### 3.2 Mixture

#### Chemical characterization (preparation):

Lyophilisate

#### Additional information:

Preparation does not contain dangerous substances above limits that need to be mentioned in this section according to applicable EU-legislation.

## Section 4. First aid measures

### 4.1 Description of first aid measures

#### 4.1.1 General notes

Dilutable with water. Remove contaminated clothing.

#### 4.1.2 Following inhalation

Supply fresh air. If you feel unwell, consult a doctor. In case of unconscious place in recovery position.

#### 4.1.3 Following skin contact

Rinse skin with soap and water. If symptoms persist, consult a doctor.

#### 4.1.4 Following eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

#### 4.1.5 Following ingestion

Give water to drink. Seek medical advice immediately. Induce vomiting.

#### 4.1.6 Self-protection of the first aider

No data available.

### 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

Treat symptomatically.

## Section 5. Firefighting measures

### 5.1 Extinguishing media

#### 5.1.1 Suitable extinguishing media

Product is non-combustible. Extinguishing materials should therefore be selected according to surrounding.

#### 5.1.2 Unsuitable extinguishing media

Not applicable.

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

Fires in the immediate vicinity may cause the development of dangerous vapours.

### 5.3 Advice for firefighters

Do not allow fire water to penetrate into surface or ground water.

## Section 6. Accidental release measures

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

Preventive skin protection recommended. Use disposable gloves. Do not swallow.

#### 6.1.1 For non-emergency personnel

No data available.

#### 6.1.2 For emergency responders

No data available.

### 6.2 Environmental precautions

Avoid emissions into soil or water. Retain contaminated water and dispose it in accordance to local regulations.

### 6.3 Methods and materials for containment and cleaning up

#### 6.3.1 Appropriate containment

Cover drains. Collect, bind and pump off spills. Collect the material for disposal in tightly closed containers.

#### 6.3.2 Clean-up procedures

Spillages should be washed with soap and water.

#### 6.3.3 Other information

No further information.

### 6.4 Reference to other sections

Refer additionally to chapter 8 and 13.

## Section 7. Handling and storage

### 7.1 Precautions for safe handling

Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Do not inhale substance. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. This product contains a substance with human origin. Even though tests on infectious diseases ended negative, this product should be handled as

potentially infectious biomaterial. Product contains bovine material. Even though tests on infectious diseases ended negative, this product should be handled as potentially infectious biomaterial. Refer additionally to section 11.

## 7.2 Conditions for safe storage, including any incompatibilities

Store according to temperature stated on the product label or according to the package insert provided. Avoid direct sunlight and temperature outside the recommended storage conditions.

## 7.3 Specific end use(s)

No data available.

# Section 8. Exposure controls / personal protection

## 8.1 Control parameters

Contains no substances with occupational exposure limit values.

## 8.2 Exposure controls

### 8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.

### 8.2.2 Personal protective equipment

Avoid skin and eye contact. Wash hands before breaks and immediately after product handling. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the workplace.



#### 8.2.2.1 Eye / face protection

Avoid skin and eye contact. No further measures need to be taken into account.

#### 8.2.2.2 Skin protection

Use appropriate disposal gloves according to EN 374. It is recommended to check the chemical resistance of the protective gloves. Also pay attention to a proper method to strip off the gloves.

### 8.2.2.3 Respiratory protection

Not relevant.

### 8.2.2.4 Thermal hazards

Not relevant.

### 8.2.3 Environmental exposure controls

Avoid emissions into soil or water.

## Section 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Mixture

#### Appearance

Physical state

solid, lyophilisate

Color

white up to yellowish

Odour

No specific odour

Odour threshold

No data available

#### Other physical and chemical parameters

pH-value

No data available

Melting point / freezing point

No data available

Initial boiling point / boiling range

No data available

Flash point

Not combustible

Evaporation rate

No data available

Flammability (solid, gas)

No data available

#### Flammability or explosive limits

Upper limit

No data available

Lower limit

No data available

Vapour pressure

No data available

Vapour density

No data available

Relative density

No data available

#### Solubility(ies)

Water solubility

Completely soluble

#### Partition coefficient

n-Octanol/water

No data available

Auto-ignition temperature

No data available

Decomposition temperature

No data available

Viscosity

No data available

Explosive properties

No data available

Oxidising properties

No data available

## 9.2 Other information

No data available.

## Section 10. Stability and Reactivity

### 10.1 Reactivity

No hazardous reactions for the mixture and the contained substances in dissolved state were observed.

### 10.2 Chemical stability

Mixture is stable under normal ambient conditions and at normal storage and handling conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reactions known.

### 10.4 Conditions to avoid

Avoid direct sunlight, vibration or high temperature.

### 10.5 Incompatible materials

Strong acids and alkalis

### 10.6 Hazardous decomposition products

Fires in the immediate vicinity may cause the development of dangerous vapours.

## Section 11. Toxicological information

### 11.1 Information on toxicological effects

#### 11.1.1 Toxicological effects

Acute toxicity (oral)	No data available
Acute toxicity (dermal)	No data available
Acute toxicity (inhalative)	No data available
Skin corrosion/irritation	No data available
Eye damage/irritation	No data available

Sensitisation to the respiratory tract	No data available
Skin sensitisation	No data available
Germ cell mutagenicity/Genotoxicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
Effects on or via lactation	No data available
STOT ( single exposure)	No data available
STOT (repeated exposure)	No data available
Aspiration hazard	No data available

### 11.1.2 Other information

This product contains a substance with human origin. Hazardous properties cannot be excluded. Donors have been tested by FDA approved methods, test results turned out negative for antibodies to HIV-1 and HIV-2, non-reactive for HBsAg, and non-reactive for HCV. Product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

## Section 12. Ecological information

### 12.1 Toxicity

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

General information: Do not allow to enter into ground-water, surface water or drains.

## 12.7 Other information

No data available.

## Section 13. Disposal considerations

### 13.1 Waste treatment methods

13.1.1 Product:

Waste key number:

16 05 06 = laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals.

Recommendation:

Special waste. Dispose of waste water according to applicable legislation.

13.1.2 Contaminated packaging:

Waste key number:

15 01 07 = Glass packaging

Recommendation:

Dispose of waste according to applicable legislation. Handle contaminated packages in the same way as the substance itself.

## Section 14. Transport information

### 14.1 UN number

Transportation of the product is not regulated by ADR.

### 14.2 UN proper shipping name

Not relevant.

### 14.3 Transport hazard class(es)

Not relevant.

### 14.4 Packaging group

Not relevant.

#### 14.5 Environmental hazards

No. (Not dangerous for the environment according to dangerous goods regulation).

#### 14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

#### 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No data available.

### Section 15. Regulatory information

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

##### Mixture

Classification, labelling and packaging of substances and mixtures (CLP)

VO (EG) Nr. 1272/2008

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

VO (EG) Nr. 2015/830

##### Regulations of the insurance funds

Federal law on occupational health and safety

BGBI.Nr. 60/2015

#### 15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for this substance / mixture by the supplier.

## Section 16. Other information

### Abbreviation

ADR	Accord européen relative au transport international des marchandises Dangereuses par Route
CLP	Classification, Labelling and Packaging
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
STOT	specific target organ toxicity

The information provided in this Safety Data Sheet is provided in the interest of promoting safe handling of the material. While this information is believed to be correct Eurolyser Diagnostica GmbH makes no warranty in respect to any of the information disclosed. Observe all federal, provincial, state and local laws concerning health and pollution.