

German and English

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

1.1 Product identifier

SAA-VET control kit, VT 1700

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

Please refer to the product insert.

1.3	Supplier's details		
Company name		Eurolyser Diagnostica GmbH	
Address, P.O. Box		Bindergasse 3	
Postcode / Place		5020 Salzburg	
Country		Austria	
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

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.

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.

EUROLyser		document	SDS SAA-VET control kit
	Safety data sheet (acc. to VO Nr. 2015/830)	created by, date	M. Quehenberger, 03.08.2020
		approved by, date	F. Helminger, 03.08.2020

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.



document

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.

Other information 6.3.3

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. 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)

EUROLyser 🕻

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

Appearance

Physical state Color Odour Odour threshold

Other physical and chemical parameters

- No data available pH-value 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 Vapour density Relative density

Solubility(ies) Water solubility

Partition coefficient n-Octanol/water

Auto-ignition temperature Decomposition temperature Viscosity Explosive properties No data available No data available No data available

<u>Mixture</u>

solid, lyophilisate

clear and pale yellow

odourless

No data available

Completely soluble

No data available

No data available No data available No data available No data available

EUROLyser 🚺		document	SDS SAA-VET control kit
	Safety data sheet (acc. to VO Nr. 2015/830)	created by, date	M. Quehenberger, 03.08.2020
		approved by, date	F. Helminger, 03.08.2020

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



document

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. 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.

Mobility in soil 12.4

No data available.

12.5 **Results of PBT and vPvB assessment**

No data available.

12.6 Other adverse effects

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

12.7 Other information

No data available.

EUROLyser	Safety data sheet (acc. to VO Nr. 2015/830)	document	SDS SAA-VET control kit
		created by, date	M. Quehenberger, 03.08.2020
		approved by, date	F. Helminger, 03.08.2020

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:

<u>Waste key number:</u>

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).

EUROLyser 🚺		document	SDS SAA-VET control kit
	Safety data sheet (acc. to VO Nr. 2015/830)	created by, date	M. Quehenberger, 03.08.2020
		approved by, date	F. Helminger, 03.08.2020

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

<u>Mixture</u>

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

<u>Regulations of the insurance funds</u>

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.



document

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.