

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) with its Amendment Annex II Regulation (EU) n° 878/2020.

## External Positive control

Version: 1.0

Revision Date: /

Date of first issue : 26/12/2022

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

**1.1 Product identifier** : This product is a mixture  
 Product name : External Positive Control (EPC)  
 Concerned : Bio-T kit® for veterinary use

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

Use of the Substance/Mixture : For in vitro diagnostic use only

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

Company : BIOSELLAL  
 27 chemin des peupliers, 69570 Dardilly, France  
 Phone : 04.26.78.47.60  
 Email contact : contact@biosellal.com

### 1.4 Emergency phone

Carechem 24 +33 (0) 1 7211 0003

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification according to REGULATION (EC) No 1272/2008 [CLP]**

| Not a hazardous substance or mixture.

### 2.2 Label elements

**Classification according to REGULATION (EC) No 1272/2008 [CLP]**

| Not a hazardous substance or mixture.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

The mixture does not contain component, substance classified hazardous.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : Show this safety data sheet to the doctor in attendance.

If inhaled : Move to fresh air.  
 If symptoms persist, call a physician.

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- In case of skin contact : Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. If symptoms persist, call a physician.
- In case of eye contact : Remove contact lenses. Protect unharmed eye. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
- If swallowed : If accidentally swallowed obtain immediate medical attention. Rinse mouth with water. Never give anything by mouth to an unconscious person.

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

The most important known symptoms and effects are described in the labelling section 2.2 and/or section 11.

Not expected to present a significant hazard under anticipated conditions of normal use.

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

- Treatment : No information available.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment (foam, dry powder, carbon dioxide)

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

Specific hazards during Firefighting : Exposure to decomposition products may be a hazard to health

Hazard product of decomposition : carbon oxide

### 5.3 Advice for firefighters

- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
- Further information : In the event of fire and/or explosion do not breathe fumes.

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## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.  
 Avoid dust formation.  
 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

### 6.2 Environmental precautions

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

Methods for cleaning up : Pick up and arrange disposal without creating dust.  
 Keep in suitable, closed containers for disposal.  
 Use mechanical handling equipment.

### 6.4 Reference to other sections

| Section 5.4 : Additional fier precautions.  
 Section 8 : Exposure controls/personal protection.  
 Section 13 : Disposal considerations.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8.  
 Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : Keep away from food and drink. When using do not eat, drink or smoke.

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

Other data : No decomposition if stored and applied as recommended.

### 7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals.  
 For in vitro diagnostic use only.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

The mixture contains no substance /component in concentration exceeding the limits (ELV) set for personal work places.

The mixture contains no substance /component concerned by biological limits value (BLV) according to regulations.

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### 8.2 Exposure controls

#### Personal protective equipment

- |                          |   |
|--------------------------|---|
| Eye protection           | : Safety glasses  |
| Hand protection          | Gloves NF EN 374: protection against chemical risks   |
| Remarks                  | : The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact). |
| Skin and body protection | : Choose body protection according to the amount and concentration of the dangerous substance at the work place. Footwear protecting against chemicals  |
| Respiratory protection   | : In case of insufficient ventilation, wear respirators and tested and approved according to the appropriate government standards   |

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: No data available
Odour	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flammability	: No data available
Upper / lower explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Viscosity, kinematic	: No data available
Solubility	: No data available
Partition coefficient n- octanol/water (log)	: No data available
Vapour pressure	: No data available
Density and/or relative density	: No data available
Relative vapour density	: No data available
Particules characteristics	: not concerned because liquid product

### 9.2 Other information

Physical hazards classes information : Mixture not classified on physical hazards

Other security characteristics : No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

| No dangerous chemical reactions known.

### 10.2 Chemical stability

| No decomposition if stored and applied as directed.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.  
Hazardous decomposition products formed under fire

### 10.4 Conditions to avoid

Conditions to avoid : No data available

### 10.5 Incompatible materials

Materials to avoid : No decomposition if stored and applied as directed.

### 10.6 Hazardous decomposition products

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No decomposition if stored and applied as directed.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

No available data on toxicological information concerning the mixture.

#### Accute toxicity

Not classified based on available information

#### Skin corrosion/irritation

Not classified based on available information.

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

#### Germ cell mutagenicity

| Not classified based on available information.

#### Carcinogenicity

| Not classified based on available information.

#### Reproductive toxicity

| Not classified based on available information.

#### STOT - single exposure

| Not classified based on available information.

#### STOT - repeated exposure

| Not classified based on available information.

#### Aspiration toxicity

| Not classified based on available information.

#### Further information

| No data available

### 11.2 Other hazard information

#### Endocrine disrupting properties

Product : the mixture does not contain components considered to have endocrine disrupting properties according to the article 57 (f) of REACH or Commission regulation (EU) 2017/2100 or Commission regulation (EU) 2018/605 at levels of 0.1% or higher.

#### Additional information

No data available

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## SECTION 12: Ecological information

### 12.1 Toxicity

**Product:**

Toxicity to fish : No data available  
 Toxicity to algae : No data available  
 Toxicity to bacteria : No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

**Product:**

Bioaccumulation : No data available

### 12.4 Mobility in soil

: No data available

### 12.5 Results of PBT and vPvB assessment

**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

The mixture does not contain components considered to have endocrine disrupting properties according to the article 57 (f) of REACH or Commission regulation (EU) 2017/2100 or Commission regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

**Product:**

Additional ecological information : No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

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

The generation of waste should be avoided or minimized wherever possible

## SECTION 14: Transport information

### IATA / ADR/RID / IMDG

Not regulated in the meaning of transport regulations

#### 14.1 UN number

| Not regulated as a dangerous good

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### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

| Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Remarks

: Not classified as dangerous in the meaning of transport regulations.

For personal protection see section 8.

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

: Not applicable

### 15.2 Chemical Safety Assessment

| No data available

## SECTION 16: Other information

Full text for H-phrase

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### Full text of other abbreviations

ELV : Exposition limit value

BLV : Biological limit value

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; ECHA - European Chemicals Agency; EC-Number - European Community number; GHS - Globally Harmonized System; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods;; ISO - International Organisation for Standardization; MARPOL - International Convention for the Prevention of Pollution from Ships; PBT - Persistent, Bioaccumulative and Toxic substance; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SDS - Safety Data Sheet; TRGS - Technical Rule for Hazardous Substances; UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative; CMR - Carcinogen, Mutagen or Reproductive Toxicant; GLP - Good Laboratory Practice

**Reason for revision** : New SDS format with updating according to Regulation (EC) No. 1907/2006 (REACH) with its Amendment Annex II Regulation (EU) n° 878/2020.

### Sources of key data used to compile the data sheet :

Regulation (EC) n°1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data are indicated directly in the corresponding section.

National threshold limits values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

### Further information

SDS number : SDSEPC001

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.