

## Erba Control N Plus

Date of creation	02. October 2017	Version	1.0
Date of revision			

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

- 1.1. Product identifier**  
Substance / mixture  
Number  
Erba Control N Plus  
mixture  
EHL00016
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**  
Intended use of the mixture  
The Erba Control N Plus may be used as a normal control for the following tests: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen 1, Anti-Thrombin (AT III), Thrombin Time (TT), Protein C, Protein S, Factors (II, V, VII, VIII, IX, X1, XI, XII2), Plasminogen, Total and Free Protein S Antigen (ELISA) - Total (%), Total and Free Protein S Antigen (ELISA) - Free (%), vWF Antigen (ELISA) (%).
- The use descriptors**  
PC 21 Laboratory chemicals  
Not recommended use of the mixture  
not available
- 1.3. Details of the supplier of the safety data sheet**  
**Manufacturer**  
Name or trade name  
Address  
Czech Republic  
Phone  
+420 517 077 111  
E-mail  
msds@erbamannheim.com  
Web address  
www.eralachema.com
- Competent person responsible for the safety data sheet**  
Name  
Erba Lachema s.r.o.  
E-mail  
msds@erbamannheim.com
- 1.4. Emergency telephone number**  
Poisoning information centre, Na Bojišti 1, Praha, Czech Republic, Tel.: non-stop +420 224 919 293 or +420 224 915 402, Information on health risks only - acute poisoning of humans and animals.

**SECTION 2: Hazards identification**

- 2.1. Classification of the substance or mixture**  
**Classification of the mixture in accordance with Regulation (EC) No 1272/2008**  
The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.  
Full text of all classifications and H-phrases is given in the section 16.
- 2.2. Label elements**  
none
- 2.3. Other hazards**  
Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

**SECTION 3: Composition/information on ingredients**

- 3.2. Mixtures**  
**Chemical characterization**  
Mixture.  
**Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment**  
none

**SECTION 4: First aid measures**

- 4.1. Description of first aid measures**  
Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

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**Inhalation**

Terminate the exposure immediately; move the affected person to fresh air.

**Skin contact**

Remove contaminated clothes.

**Eye contact**

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

**Ingestion**

Rinse out the mouth with clean water. In the event of issues, find medical help.

**4.2. Most important symptoms and effects, both acute and delayed****Inhalation**

Not expected.

**Skin contact**

Not expected.

**Eye contact**

Not expected.

**Ingestion**

Not expected.

**4.3. Indication of any immediate medical attention and special treatment needed**

Symptomatic treatment.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

Accommodate extinguishing components to the location of fire.

**Unsuitable extinguishing media**

Not known.

**5.2. Special hazards arising from the substance or mixture**

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

**5.3. Advice for firefighters**

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Follow the instructions in the Sections 7 and 8.

**6.2. Environmental precautions**

Prevent contamination of the soil and entering surface or ground water.

**6.3. Methods and material for containment and cleaning up**

After removal of the product, wash the contaminated site with plenty of water.

**6.4. Reference to other sections**

See the Section 7, 8 and 13.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

**7.2. Conditions for safe storage, including any incompatibilities**

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

Storage temperature

min 2 °C, max 8 °C

**7.3. Specific end use(s)**

For in vitro diagnostic devices.

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**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

none

**8.2. Exposure controls**

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

**Eye/face protection**

It is not needed.

**Skin protection**

When handling in long-term or repeatedly, use protective gloves.

**Respiratory protection**

It is not needed.

**Thermal hazard**

Not available.

**Environmental exposure controls**

Observe usual measures for protection of the environment, see Section 6.2.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

## Appearance

Physical state

solid at 20°C

color

data not available

Odour

data not available

Odour threshold

data not available

pH

data not available

Melting point/freezing point

data not available

Initial boiling point and boiling range

data not available

Flash point

data not available

Evaporation rate

data not available

Flammability (solid, gas)

data not available

Upper/lower flammability or explosive limits

flammability limits

data not available

explosive limits

data not available

Vapour pressure

data not available

Vapour density

data not available

Relative density

data not available

Solubility(ies)

solubility in water

data not available

solubility in fats

data not available

Partition coefficient: n-octanol/water

data not available

Auto-ignition temperature

data not available

Decomposition temperature

data not available

Viscosity

data not available

Explosive properties

data not available

Oxidising properties

data not available

**9.2. Other information**

Density

data not available

ignition temperature

data not available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

not available

**10.2. Chemical stability**

The product is stable under normal conditions.

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**10.3. Possibility of hazardous reactions**

Unknown.

**10.4. Conditions to avoid**

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

**10.5. Incompatible materials**

Protect against strong acids, bases and oxidizing agents.

**10.6. Hazardous decomposition products**

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects**

No toxicological data is available for the mixture.

**Acute toxicity**

Based on available data the classification criteria are not met.

**Skin corrosion/irritation**

Based on available data the classification criteria are not met.

**Serious eye damage/irritation**

Based on available data the classification criteria are not met.

**Respiratory or skin sensitisation**

Based on available data the classification criteria are not met.

**Germ cell mutagenicity**

Based on available data the classification criteria are not met.

**Carcinogenicity**

Based on available data the classification criteria are not met.

**Reproductive toxicity**

Based on available data the classification criteria are not met.

**Toxicity for specific target organ - single exposure**

Based on available data the classification criteria are not met.

**Toxicity for specific target organ - repeated exposure**

Based on available data the classification criteria are not met.

**Aspiration hazard**

Based on available data the classification criteria are not met.

**SECTION 12: Ecological information****12.1. Toxicity****Acute toxicity**

Data for the mixture are not available.

**12.2. Persistence and degradability**

Data not available.

**12.3. Bioaccumulative potential**

Not available.

**12.4. Mobility in soil**

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Not available.

**12.5. Results of PBT and vPvB assessment**

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

**12.6. Other adverse effects**

Not available.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

**Legislation of waste**

Council Directive 75/442/EEC on waste, as amended. Decree No. 383/2001 Coll., on details regarding waste handling as amended. Decree No. 93/2016 Coll., (waste catalogue) as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

**SECTION 14: Transport information****14.1. UN number**

Not subject to ADR.

**14.2. UN proper shipping name**

not available

**14.3. Transport hazard class(es)**

not available

**14.4. Packing group**

not available

**14.5. Environmental hazards**

not available

**14.6. Special precautions for user**

Reference in the Sections 4 to 8.

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

not available

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006, as amended. The Act No. 350/2011 Coll., on Chemical Substances and Chemical Preparations as amended (the Chemical Act). Decree No. 432/2003 Coll., laying down conditions for assigning categories to individual jobs, limit values of indices from biological exposure tests, conditions for the sampling of biological materials for biological exposure and the particulars of the reports on work with asbestos and biological agents as amended.

**15.2. Chemical safety assessment**

Assessment was not carried out.

**SECTION 16: Other information****Other important information about human health protection**

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

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**Key to abbreviations and acronyms used in the safety data sheet**

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
DNEL	Derived no-effect level
EC	Identification code for each substance listed in EINECS
EC <sub>50</sub>	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
IC <sub>50</sub>	Concentration causing 50% blockade
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC <sub>50</sub>	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD <sub>50</sub>	Lethal dose of a substance in which it can be expected death of 50% of the population
LOAEC	Lowest observed adverse effect concentration
LOAEL	Lowest observed adverse effect level
log K <sub>ow</sub>	Octanol-water partition coefficient
MARPOL	International Convention for the Prevention of Pollution From Ships
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
NOEL	No observed effect level
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
PNEC	Predicted no-effect concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative

**Training guidelines**

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

**Recommended restrictions of use**

For in vitro diagnostic use only.

**Information about data sources used to compile the Safety Data Sheet**

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REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. The Act No. 350/2011 Coll., on Chemical Substances and Chemical Preparations as amended. First aid principles after the exposure to the chemicals (Zásady pro poskytování první pomoci při expozici chemickým látkám, doc. MUDr. Daniela Pelclová, CSc., MUDr. Alexandr Fuchs, CSc., MUDr. Miroslava Hornychová, CSc., MUDr. Zdeňka Trávníčková, CSc., Jiřina Fridrichovská, prom. chem.). Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

**Statement**

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.