

## Erba DDimer R\_R2

Creation date	06th October 2017		
Revision date	20th November 2023	Version	3.0

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

- 1.1. Product identifier**  
Substance / mixture Erba DDimer R\_R2  
Number mixture  
Other mixture names EHL00011, EHL00028, EHL00049  
Erba DDimer R33, Erba DDimer R11, Erba DDimer R60, DDimer Latex
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**  
**Mixture's intended use**  
Reagent 2 is a part of Erba DDimer R kit, which is an immunoturbidimetric assay used for the quantitative determination of the fibrin degradation products that contain D-dimer in human plasma.  
**Main intended use**  
PC-MED-OTH Other medical devices  
**Secondary uses**  
PC-TEC-19 Reagents and laboratory chemicals  
**The use descriptors**  
PC 21 Laboratory chemicals  
**Mixture uses advised against**  
not available
- 1.3. Details of the supplier of the safety data sheet**  
**Manufacturer**  
Name or trade name Erba Lachema s.r.o.  
Address Karásek 2219/1d , Brno, 62100  
Czech Republic  
Identification number (CRN) 26918846  
VAT Reg No CZ26918846  
Phone +420 517 077 111  
E-mail msds@erba.com  
Web address www.erbalachema.com  
**Competent person responsible for the safety data sheet**  
Name Erba Lachema s.r.o.  
E-mail msds@erba.com
- 1.4. Emergency telephone number**  
European emergency number: 112 112

**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 hazard statements is given in the section 16.
- 2.2. Label elements**  
**Supplemental information**  
EUH210 Safety data sheet available on request.  
EUH208 Contains 2-methylisothiazol-3(2H)-one. May produce an allergic reaction.
- 2.3. Other hazards**  
The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. 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.

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**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Mixture of substances and additives specified below.

**Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment**

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	<0,1	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	1
Index: 613-326-00-9 CAS: 2682-20-4 EC: 220-239-6	2-methylisothiazol-3(2H)-one	<0,0015	Acute Tox. 3, H301, H311 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Eye Dam. 1, H318 Acute Tox. 2, H330 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH071 Specific concentration limit: Skin Sens. 1A, H317: C ≥ 0.0015 %	

**Notes**

1 A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

**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.

**If inhaled**

Terminate the exposure immediately; move the affected person to fresh air. Rinse nose, mouth and throat with water. If symptoms remain, obtain medical attention.

**If on skin**

Remove contaminated clothes. Wash with soap and water. If symptoms remain, obtain medical attention.

**If in eyes**

Rinse immediately with water for 10-15 minutes while keeping the eyes wide open. If symptoms remain, obtain medical attention.

**If swallowed**

Never give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Do not induce vomiting. Have victim drink 200-400 mL water to dilute. Obtain medical attention.

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

Not expected.

**If on skin**

Not expected.

**If in eyes**

Not expected.

**If swallowed**

Not expected.

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

Symptomatic treatment.

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

The product is non-combustible. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. For example: water spray jet, foam, carbon dioxide, dry powder.

**Unsuitable extinguishing media**

Among common extinguishing agents there are none that are overtly unsuitable.

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

Inhalation of hazardous degradation 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. Wear suitable protective clothing. Prevent skin and eye contact.

**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**

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Do not to eat, drink and smoke in work areas.

Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas. Prevent skin and eye contact.

**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. Do not freeze.

Storage temperature min 2 °C, max 8 °C

**The specific requirements or rules relating to the substance/mixture**

This product is for in vitro diagnostic use only and should be used by trained personnel.

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

not available

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

The mixture contains substances for which occupational exposure limits are set.

**Czech Republic****Government Regulation 195/2021 Coll.**

Substance name (component)	Type	Value	Conversion for ppm	Note
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m <sup>3</sup>	0,370	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin

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## Czech Republic

## Government Regulation 195/2021 Coll.

Substance name (component)	Type	Value	Conversion for ppm	Note
sodium azide (CAS: 26628-22-8)	NPK-P	0,3 mg/m <sup>3</sup>	0,370	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin

## European Union

## Commission Directive 2000/39/EC

Substance name (component)	Type	Value	Note
sodium azide (CAS: 26628-22-8)	OEL 8 hours	0,1 mg/m <sup>3</sup>	Skin
	OEL 15 minutes	0,3 mg/m <sup>3</sup>	

## United Kingdom

## EH40/2005 Workplace exposure limits (Fourth Edition 2020)

Substance name (component)	Type	Value	Note
sodium azide (as NaN <sub>3</sub> ) (CAS: 26628-22-8)	WEL 8h	0,1 mg/m <sup>3</sup>	Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.
	WEL 15min	0,3 mg/m <sup>3</sup>	

## 8.2. Exposure controls

Good general ventilation. Use good hygiene practices. 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. Avoid contact with eyes and skin.

**Eye/face protection**

Safety goggles are recommended.

**Skin protection**

When handling in long-term or repeatedly, use protective gloves. Disposable gloves are recommended (vinyl, latex).

**Respiratory protection**

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

**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

Physical state	liquid
Colour	white
Odour	odourless
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	non-flammable

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Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	8.5 (undiluted at 20 °C)
Kinematic viscosity	data not available
Solubility in water	data not available
Solubility in fats	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

**9.2. Other information**

Evaporation rate	data not available
Explosive properties	The product does not have explosive properties.

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

Not reactive.

**10.2. Chemical stability**

The product is stable under normal conditions.

**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. However, freezing as well as storage of the product at elevated temperature may affect the product and reduce its function.

**10.5. Incompatible materials**

Protect against strong acids, bases and oxidizing agents.

**10.6. Hazardous decomposition products**

Not developed under normal uses.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

**Acute toxicity**

Based on the available data, the criteria for classification of the mixture are not met. Data for the components of the mixture are not available.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	9986 mg/kg				Calculation of value
Dermal	ATE	20690000 mg/kg				Calculation of value
Inhalation (vapor)	ATE	34480 mg/l				Calculation of value

**Skin corrosion/irritation**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

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**Serious eye damage/irritation**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Respiratory or skin sensitisation**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Germ cell mutagenicity**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Carcinogenicity**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Reproductive toxicity**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

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

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

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

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Aspiration hazard**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**11.2. Information on other hazards**

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

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

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**12.2. Persistence and degradability**

No data are available for either the mixture or the components.

**12.3. Bioaccumulative potential**

No data are available for either the mixture or the components.

**12.4. Mobility in soil**

No data are available for either the mixture or the components.

**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. Endocrine disrupting properties**

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

**12.7. Other adverse effects**

Not available.

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**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.

**Waste management legislation**

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

**Waste type code**

16 05 06 laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals \*

**Packaging waste type code**

15 01 10 packaging containing residues of or contaminated by hazardous substances \*

(\*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

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

not subject to transport regulations

**14.2. UN proper shipping name**

not relevant

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

not relevant

**14.4. Packing group**

not relevant

**14.5. Environmental hazards**

not relevant

**14.6. Special precautions for user**

Reference in the Sections 4 to 8.

**14.7. Maritime transport in bulk according to IMO instruments**

not relevant

**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 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. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

**National regulations (Germany)**

WGK Water hazard class: nwg - non-hazardous to water

**15.2. Chemical safety assessment**

not available

**SECTION 16: Other information**

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**A list of standard risk phrases used in the safety data sheet**

H300	Fatal if swallowed.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

**A list of additional standard phrases used in the safety data sheet**

EUH210	Safety data sheet available on request.
EUH208	Contains 2-methylisothiazol-3(2H)-one. May produce an allergic reaction.
EUH032	Contact with acids liberates very toxic gas.
EUH071	Corrosive to the respiratory tract.

**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.

**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
EC	Identification code for each substance listed in EINECS
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
log K <sub>ow</sub>	Octanol-water partition coefficient
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
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
Acute Tox.	Acute toxicity
Aquatic Acute	Hazardous to the aquatic environment



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Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Eye Dam.	Serious eye damage
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization

**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**

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. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

**The changes (which information has been added, deleted or modified)**

The version 3.0 replaces the SDS version from 19 February 2021. Changes were made in sections 1, 2, 11, 12, 15 and 16.

**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.