

## HDL/LDL CAL

Creation date

01st August 2023

Revision date

Version

1.0

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

HDL/LDL CAL

Substance / mixture

mixture

Number

XSYS0061

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Mixture's intended use**

HDL/LDL Calibrator is intended for quantitative determination of HDL and LDL cholesterol using a HDL and LDL Direct reagent.

**Main intended use**

PC-MED-OTH

Other medical devices

**Secondary uses**

PC-TEC-19

Reagents and laboratory chemicals

**Mixture uses advised against**

The product should not be used in ways other than those referred in Section 1.

**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**

none

**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.

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

**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.

## HDL/LDL CAL

Creation date

01st August 2023

Revision date

Version

1.0

**If inhaled**

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

**If on skin**

Remove contaminated clothes.

**If in eyes**

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.

**If swallowed**

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****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.

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

Accommodate extinguishing components to the location of fire.

**Unsuitable extinguishing media**

not available

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

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)**

not available

## HDL/LDL CAL

Creation date

01st August 2023

Revision date

Version

1.0

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

The mixture contains no substances for which occupational exposure limits are set.

**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**

Safety goggles are recommended.

**Skin protection**

Hand protection: Protective gloves resistant to the product. When handling in long-term or repeatedly, use protective gloves.

**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   | data not available            |
| Odour  | data not available            |
| Melting point/freezing point                             | data not available            |
| Boiling point or initial boiling point and boiling range | data not available            |
| Flammability   | The product is non-flammable. |
| Lower and upper explosion limit                          | data not available            |
| Flash point  | not applicable                |
| Auto-ignition temperature                                | data not available            |
| Decomposition temperature                                | data not available            |
| pH   | data not available            |
| Kinematic viscosity                                      | data not available            |
| Solubility in water                                      | 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**

not available

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

not available

**10.2. Chemical stability**

The product is stable under normal conditions.

**10.3. Possibility of hazardous reactions**

Unknown.

## HDL/LDL CAL

Creation date

01st August 2023

Revision date

Version

1.0

**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.

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

No toxicological data is available for the mixture.

**Acute 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.

**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.

**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.

## HDL/LDL CAL

Creation date

01st August 2023

Revision date

Version

1.0

**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.

**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.

**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

## HDL/LDL CAL

Creation date

01st August 2023

Revision date

Version

1.0

**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).

**15.2. Chemical safety assessment**

not available

**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.

**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 Kow | Octanol-water partition coefficient   |
| OEL     | Occupational Exposure Limits  |
| PBT     | Persistent, Bioaccumulative and Toxic   |
| 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**

**HDL/LDL CAL**

Creation date

01st August 2023

Revision date

Version

1.0

not available

**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.

**More information**

Classification procedure - calculation method.

**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.