

## LDL CHOLESTEROL DIRECT\_R2

Creation date	07th January 2019	Version	3.0
Revision date	04th January 2024		

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

- 1.1. Product identifier**  
Substance / mixture LDL CHOLESTEROL DIRECT\_R2  
Number mixture  
Other mixture names BLT00043; BLT00042  
LDL C DIRECT 80; LDL C DIRECT 240
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**  
**Mixture's intended use**  
Diagnostic reagent for quantitative in vitro determination of LDL Cholesterol in human serum and plasma.  
**Main intended use**  
PC-MED-OTH Other medical devices  
**Secondary uses**  
PC-TEC-19 Reagents and 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.
- 2.2. Label elements**  
none  
**Supplemental information**  
EUH210 Safety data sheet available on request.  
EUH208 Contains Alcohols, C11-15-secondary, ethoxylated. 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
CAS: 68131-40-8 EC: 614-295-4	Alcohols, C11-15-secondary, ethoxylated	<1	Acute Tox. 4, H302+H332 Skin Irrit. 2, H315 Skin Sens. 1B, H317 Eye Dam. 1, H318 Aquatic Chronic 3, H412 Specific concentration limit: ATE Oral = 2000 mg/kg bw ATE Inhalation (vapor) = 11 mg/l	

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.

**If on skin**

Remove contaminated clothes. Wash with plenty of soap and water.

**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. Do not induce vomiting. 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. Water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO<sub>2</sub>).**Unsuitable extinguishing media**

Water - full jet.

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

Fires in the immediate vicinity may cause the development of dangerous vapours. In case of fire may be liberated: nitrogen oxides (NO<sub>x</sub>), carbon monoxide and carbon dioxide.

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**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. In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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

Follow the instructions in the Sections 7 and 8. Observe the principles of work safety in chemical laboratories. Prevent contact with skin and eyes. Do not inhale gases and vapours.

**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**

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per Section 13. Collected material should be disposed of in accordance with locally valid regulations. After removal of the product, wash the contaminated site with plenty of water. Place in appropriate containers for disposal. Ventilate affected area.

**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 store together with food, drink and animal feed. Use local and general ventilation. Avoid release to the environment. Wash hands after use. Preventive skin protection (barrier creams/ointments) is recommended. Remove contaminated clothing and protective equipment before entering eating areas.

**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. Protect against external exposure, such as heat, frost, UV-radiation/sunlight. Keep away from food, drink and animal feedingstuffs. Provision of sufficient ventilation. Keep only in original container.

Storage temperature min 2 °C, max 8 °C

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

The kit is designed for in vitro diagnostic devices.

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

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

**PNEC**

Alcohols, C11-15-secondary, ethoxylated			
Route of exposure	Value	Value determination	Source
Drinking water	0.002 mg/l		
Marine water	0 mg/l		
Freshwater environment	0.015 mg/l		
Microorganisms in sewage treatment	8.24 mg/l		
Freshwater sediment	64.3 mg/kg		
Soil (agricultural)	12.9 mg/kg		
Sea sediments	6.43 mg/kg		

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**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**

Wear eye/face protection.

**Skin protection**

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use.

In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

**Respiratory protection**

Under good ventilation/ exhaustion at the workplace, the use of these products should not require respiratory protection.

**Thermal hazard**

Not available.

**Environmental exposure controls**

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

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

Physical state	liquid
Colour	yellowish brown
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	data not available
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
Form	brown-yellow liquid

**9.2. Other information**

Oxidising properties	The product has no oxidizing properties.
Explosive properties	The product does not have explosive properties.

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

This material is not reactive under normal ambient conditions.

**10.2. Chemical stability**

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

**10.3. Possibility of hazardous reactions**

No known hazardous reactions.

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**10.4. Conditions to avoid**

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

**10.5. Incompatible materials**

There is no additional information.

**10.6. Hazardous decomposition products**

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

**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.

**Alcohols, C11-15-secondary, ethoxylated**

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	ATE	2000 mg/kg bw			
Inhalation (vapor)	ATE	11 mg/l			

**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**

Contains Alcohols, C11-15-secondary, ethoxylated. May produce an allergic reaction.

**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.

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**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**

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

**Acute toxicity**

Alcohols, C11-15-secondary, ethoxylated				
Parameter	Value	Exposure time	Species	Environment
LD <sub>50</sub>	1.53 mg/l	96 hours	Fish	
EC <sub>50</sub>	5.66 mg/l	48 hours	Aquatic invertebrates	

**Chronic toxicity**

Alcohols, C11-15-secondary, ethoxylated				
Parameter	Value	Exposure time	Species	Environment
EC <sub>50</sub>	824 mg/l	3 hours	Microorganisms	
NOEC	0.6 mg/l	21 days	Daphnia (Daphnia magna)	

**More information**

Test data are not available for the complete mixture.

**12.2. Persistence and degradability**

Alcohols, C11-15-secondary, ethoxylated:  
oxygen depletion 65% 28 day

**12.3. Bioaccumulative potential**

Data for the mixture are not available.

Alcohols, C11-15-secondary, ethoxylated					
Parameter	Value	Exposure time	Species	Environment	Temperature [°C]
Log Kow	5.9				25°C

**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**

Wassergefährdungsklasse, WGK (water hazard class): 1

**SECTION 13: Disposal considerations**

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**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

(\*) - 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).

**15.2. Chemical safety assessment**

not available

**SECTION 16: Other information****A list of standard risk phrases used in the safety data sheet**

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H412	Harmful to aquatic life with long lasting effects.
H302+H332	Harmful if swallowed or if inhaled.

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

EUH210	Safety data sheet available on request.
EUH208	Contains Alcohols, C11-15-secondary, ethoxylated. May produce an allergic reaction.

**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
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
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
LD <sub>50</sub>	Lethal dose of a substance in which it can be expected death of 50% of the population
log K <sub>ow</sub>	Octanol-water partition coefficient
NOEC	No observed effect concentration
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
Acute Tox.	Acute toxicity
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Eye Dam.	Serious eye damage
Skin Irrit.	Skin irritation
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**

not available

**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. 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 18 June 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.