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

1.1. Product identifier — HDL CHOLESTEROL CALIBRATOR

Substance / mixture	mixture
Number	BLT00072
UFI	N8WG-MWMS-TJ59-08EN

Other mixture names

HDL C CAL

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

Mixture's intended use

The reagent is intended for the quantitative determination of HDL cholesterol by the HDL C DIRECT 240 test in human serum.

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 classified as dangerous.

Skin Sens. 1A, H317

Most serious adverse effects on human health and the environment

May cause an allergic skin reaction.

2.2. Label elements

Hazard pictogram

Signal word

Warning

Hazardous substances

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one

Hazard statements

H317 — May cause an allergic skin reaction.

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

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. Dust may form explosive mixture with air.

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: 613-167-00-5 CAS: 55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one	<0,06	Acute Tox. 3, H301 Acute Tox. 2, H310+H330 Skin Corr. 1C, H314 Skin Sens. 1A, H317 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071 Specific concentration limit: Eye Irrit. 2, H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1A, H317: C ≥ 0.0015 % Skin Irrit. 2, H315: 0.06 % ≤ C < 0.6 % Skin Corr. 1C, H314: C ≥ 0.6 % Eye Dam. 1, H318: C ≥ 0.6 % ATE Oral = 67 mg/kg bw ATE Dermal = 140 mg/kg bw ATE Inhalation (vapor) = 0,17 mg/l ATE Inhalation (dust/mist) = 0,005 mg/l	1, 2

Notes

1 Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid … %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

2 The use of the substance is restricted by Annex XVII of REACH Regulation

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. Remove contaminated clothes immediately.

If inhaled

Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

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. Rinsing should continue at least for 10 minutes.

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

May cause an allergic skin reaction.

If in eyes

Not expected.

If swallowed

Irritation, nausea.

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

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

Deposited combustible dust has considerable explosion potential. Hazardous combustion products: carbon monoxide (CO), carbon dioxide (CO2), sulphur oxides (SOx).

5.3. Advice for firefighters

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.
Special protective equipment for firefighters: use suitable breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Prevent contact with skin and eyes. Ventilate affected area.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

6.3. Methods and material for containment and cleaning up

Collect spillage, collect in tightly closed containers and dispose of according to section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

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 contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Use local and general ventilation. Keep away from sources of ignition - No smoking. Avoid release to the environment. Do not eat, drink and smoke in work areas. 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.

Storage temperature min 2 °C, max 8 °C

7.3. Specific end use(s)

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.

DNEL

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one					
Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	0.02 mg/m³	Chronic effects local		
Consumers	Inhalation	0.02 mg/m³	Chronic effects local		
Consumers	Oral	0.09 mg/kg bw/day	Chronic effects systemic		

PNEC

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one			
Route of exposure	Value	Value determination	Source
Drinking water	3.39 µg/l		
Marine water	3.39 µg/l		
Microorganisms in sewage treatment	0.23 mg/l		
Freshwater sediment	0.027 mg/kg		
Sea sediments	0.027 mg/kg		
Soil (agricultural)	0.01 mg/kg		

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. General ventilation.

Eye/face protection

Wear eye/face protection.

Skin protection

Hand protection: Protective gloves resistant to the product. Contaminated skin should be washed thoroughly.

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. 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	solid (lyofilizát)
Colour	pale yellow
Odour	nearly odourless
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	100 °C
Flammability	this material is combustible, but will not ignite
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
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
Form	pale yellow lyophilisate

9.2. Other information

Evaporation rate	data not available
Oxidising properties	It is not oxidising.
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 product is stable under normal conditions.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

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

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

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD_{50}	64 mg/kg		Rat	
Dermal	LD_{50}	87.12 mg/kg		Rabbit	
Inhalation	LC_{50}	0.33 mg/l	4 hours	Rat	
Oral	ATE	67 mg/kg bw			
Dermal	ATE	140 mg/kg bw			
Inhalation (vapor)	ATE	0.17 mg/l			
Inhalation (dust/mist)	ATE	0.005 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

May cause an allergic skin reaction. Data for the components of the mixture are not available.

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

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

Acute toxicity

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one				
Parameter	Value	Exposure time	Species	Environment
LC_{50}	0.19 mg/l	96 hours	Fish (Oncorhynchus mykiss)	
EC_{50}	0.16 mg/l	48 hours	Daphnia (Daphnia magna)	
EC_{50}	0.018 mg/l	72 hours	Algae (Pseudokirchneriella subcapitata)	
ErC_{50}	19.9 µg/l	72 hours	Algae	

Chronic toxicity

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one				
Parameter	Value	Exposure time	Species	Environment
NOEC	>46.4 µg/l	35 days	Fish	
LC_{50}	0.07 mg/l	14 days	Fish	
EC_{50}	0.18 mg/l	21 days	Aquatic invertebrates	
ErC_{50}	45.6 µg/l	120 hours	Algae	
LOEL	0.06 mg/l	36 days	Fish	
LOEC	0.144 mg/l	28 days	Fish	

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

Data for the mixture are not available.

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one					
Parameter	Value	Exposure time	Species	Environment	Temperature [°C]
Log Kow	0.34-0.63				10°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): 3

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

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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).

Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one

Restriction	Conditions of restriction
03	1. Shall not be used in: — ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, — tricks and jokes, — games for one or more participants, or any article intended to be used as such, even with ornamental aspects, 2. Articles not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they: — can be used as fuel in decorative oil lamps for supply to the general public, and — present an aspiration hazard and are labelled with H304. 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN). 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met: (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage"; (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage'; (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.

15.2. Chemical safety assessment

not available

SECTION 16: Other information

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

H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H310+H330	Fatal in contact with skin or if inhaled.

Guidelines for safe handling used in the safety data sheet

P280	Wear protective gloves/protective clothing/eye protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

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

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
EC_{50}	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
LC_{50}	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD_{50}	Lethal dose of a substance in which it can be expected death of 50% of the population
log Kow	Octanol-water partition coefficient
NOEC	No observed effect concentration
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
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

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.

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

The version 4.0 replaces the SDS version from 12 July 2021. Changes were made in sections 2, 11, 12, 15 and 16.

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.