

## HDL PREC 100\_R2

Creation date	03rd May 2016	Version	4.0
Revision date	21st March 2024		

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

Substance / mixture	HDL PREC 100_R2
Number	mixture
UFI	BLT00032
Other mixture names	S28F-EE22-TH7A-VC80
	HDL PREC 100 (STD)

**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 HDL Cholesterol in human serum and 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 classified as dangerous.

Eye Dam. 1, H318

**Most serious adverse physico-chemical effects**

Unknown

**Most serious adverse effects on human health and the environment**

Causes serious eye damage.

**2.2. Label elements****Hazard pictogram****Signal word**

Danger

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**Hazardous substances**

Triton X-100

**Hazard statements**

H318

Causes serious eye damage.

**Precautionary statements**

P280

Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310

Immediately call a doctor.

**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****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: 9002-93-1 EC: 618-344-0	Triton X-100	<11	Acute Tox. 4, H302 Eye Dam. 1, H318	3, 4
Index: 603-002-00-5 CAS: 64-17-5 EC: 200-578-6	ethanol	3,7	Flam. Liq. 2, H225	1
Index: 603-001-00-X CAS: 67-56-1 EC: 200-659-6	methanol	0,2	Flam. Liq. 2, H225 Acute Tox. 3, H301+H311+H331 STOT SE 1 (**), H370 Specific concentration limit: STOT SE 1, H370: C ≥ 10 % STOT SE 2, H371: 3 % ≤ C < 10 %	1, 2, 5
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

**Notes**

\*\* another exposure route cannot be ruled out

1 A substance for which exposure limits are set.

2 Substance for which biological limit values exist.

3 Substance of very high concern - SVHC.

4 The substance is included in Annex XIV of the REACH Regulation

5 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. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

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**If inhaled**

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

**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. No neutralization should be performed in any case! Rinsing should be continued for 10-30 minutes from the inner to the outer eye corner to make sure that the other eye is not involved. Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible. Everyone must be referred for treatment even if affected only a little.

**If swallowed**

Rinse mouth with water, drink 1/2 l of lukewarm 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**

Inhaling vapours can cause corrosion of the breathing system. Possible irritation of airways, cough, headache.

**If on skin**

Irritant effects.

**If in eyes**

Causes serious eye damage.

**If swallowed**

Corrosion of the digestion system can occur. 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. Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

**Unsuitable extinguishing media**

Water - full jet.

**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 a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

**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. Observe the principles of work safety in chemical laboratories.

**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 the 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.

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

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Prevent contact with skin and eyes. 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. Do not expose to sunlight.

Storage class

8B - Non-combustible corrosive substances

Storage temperature

min 2 °C, max 8 °C

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

Solvent vapours are heavier than air and accumulate especially near the floor where they may form an explosive mixture with the air.

**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 substances for which occupational exposure limits are set.

**Czech Republic****Government Regulation 330/2023 Coll.**

Substance name (component)	Type	Value	Note
ethanol (CAS: 64-17-5)	PEL	1000 mg/m <sup>3</sup>	
	PEL	522 ppm	
	NPK-P	3000 mg/m <sup>3</sup>	
	NPK-P	1566 ppm	
methanol (CAS: 67-56-1)	PEL	250 mg/m <sup>3</sup>	skin penetration is significantly involved during exposure
	PEL	188 ppm	
	NPK-P	1000 mg/m <sup>3</sup>	
	NPK-P	751 ppm	
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m <sup>3</sup>	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	0,3 mg/m <sup>3</sup>	

**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>	

**European Union****Commission Directive 2006/15/EC**

Substance name (component)	Type	Value	Note
methanol (CAS: 67-56-1)	OEL 8 hours	260 mg/m <sup>3</sup>	Skin

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## European Union

## Commission Directive 2006/15/EC

Substance name (component)	Type	Value	Note
methanol (CAS: 67-56-1)	OEL 8 hours	200 ppm	Skin

## Biological limit values

## Czech Republic

## Decree No. 107/2017 Coll.

Name	Parameter	Value	Tested material	Time of sampling
methanol (CAS: 67-56-1)	methanol	15 mg/l	Urine	End of shift
		0,47 mmol/l		

## 8.2. Exposure controls

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. 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

Protective goggles.

## Skin protection

Hand protection: Protective gloves resistant to the product. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. Observe other recommendations of the manufacturer. Other protection: protective workwear. 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.

## SECTION 9: Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
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	clear

## 9.2. Other information

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

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

The mixture is non-flammable.

**10.2. Chemical stability**

The product is stable under normal conditions.

**10.3. Possibility of hazardous reactions**

The product is stable under normal conditions.

**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 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.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	3732 mg/kg				Calculation of value
Dermal	ATE	150000 mg/kg				Calculation of value
Inhalation (vapor)	ATE	1500 mg/l				Calculation of value

sodium azide						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD <sub>50</sub>	27 mg/kg bw				
Inhalation	LC <sub>50</sub>	54 mg/m <sup>3</sup>	4 hours	Rat		

Triton X-100						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD <sub>50</sub>	5900 mg/kg		Rat (Rattus norvegicus)		

**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**

Causes serious eye damage. Data for the components of the mixture are not available.

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**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**

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

**Acute toxicity**

sodium azide				
Parameter	Value	Exposure time	Species	Environment
LC <sub>50</sub>	680 µg/l		Fish	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	400 µg/l		Invertebrates	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	150 µg/l		Invertebrates	Salt water
EC <sub>50</sub> /LC <sub>50</sub>	348 µg/l		Algae	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	5.6 mg/l		Microorganisms	
NOEC	30 µg/l		Microorganisms	

**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**

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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.

**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).



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

methanol

Restriction	Conditions of restriction
69	Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.

**15.2. Chemical safety assessment**

not available

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

H225	Highly flammable liquid and vapour.
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H370	Causes damage to organs.
H371	May cause damage to organs.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H301+H311+H331	Toxic if swallowed, 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/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a doctor.

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

EUH032	Contact with acids liberates very toxic gas.
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**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
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
log Kow	Octanol-water partition coefficient

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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
Flam. Liq.	Flammable liquid
STOT SE	Specific target organ toxicity - single exposure

**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 professional 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 4.0 replaces the SDS version from 29 August 2022. Changes were made in sections 2, 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.