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

1.1 Product identifier

<table>
<thead>
<tr>
<th>CHOLESTEROL</th>
<th>Pack Name</th>
<th>CHOL 440</th>
<th>CHOL 5x50</th>
<th>CHOL 1000</th>
<th>CHOL 250</th>
<th>CHOL 576 XL-1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat. No.</td>
<td>XSYS0009</td>
<td>BLT00034</td>
<td>BLT00035</td>
<td>BLT00036</td>
<td>XSYS0070</td>
<td></td>
</tr>
<tr>
<td>Reagent 1</td>
<td>10x44 ml</td>
<td>5x50 ml</td>
<td>1x1000 ml</td>
<td>1x250 ml</td>
<td>8x72 ml</td>
<td></td>
</tr>
</tbody>
</table>

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

Diagnostic reagent for quantitative \textit{in vitro} determination of Cholesterol in human serum and plasma.

1.3 Details of the supplier of the safety data sheet

Name of manufacturer: Erba Lachema s.r.o.
Place of business: Brno, Karásek 1d, postcode 621 00, CZ
ID no: 26918846
Phone: +420 517 077 111
E-mail: msds@erbalachema.com

1.4 Emergency telephone number

Erba Lachema s.r.o.
Phone: +420 517 077 556 \textit{(service only during business hours)}

Toxicological Information Centre (TIS), Na Bojišti 1, 128 01 Prague 2
Phone: +420 224 919 293 or +420 224 915 402 \textit{(service available 24 hours a day)}

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Reagent 1

Classification according to Regulation (EC) No 1272/2008
Mixture is not classified as hazardous.

2.2 Label elements

The product does not need to be labelled in accordance with EC directives.

2.3 Other hazards

Mixture or components are not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

The product is a mixture.
3.2 Mixtures

Reagent 1 contains following hazardous substances:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Content (% of weight)</th>
<th>CAS number</th>
<th>EC number</th>
<th>Index number</th>
<th>Reg. number</th>
<th>Specific Concentration limits, M-factors</th>
<th>Classification according to 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-morpholino propanesulfonic acid</td>
<td>1.0</td>
<td>1132-61-2</td>
<td>214-478-5</td>
<td>–</td>
<td>–</td>
<td>Skin Irrit. 2 Eye Irrit. 2 STOT SE 3</td>
<td>H315 H319 H335</td>
</tr>
</tbody>
</table>

For a full text of H-statements see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

No special measures required.

Exposure by inhalation

Discontinue the exposure.

Exposure by contact with skin

After contact with skin, wash with soap and water.

Exposure by contact with eyes

Rinse an open eye (hold eyelids with fingers) with plenty of water for about 15 minutes.

Exposure by ingestion

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

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

The mixture is not flammable. The measure should be adapted to burning substances in the surrounding area.

5.1 Extinguishing media

Suitable extinguishing media:

Use any extinguishing media appropriate to fire conditions.

5.2 Special hazards arising from the substance or mixture

None known.

5.3 Advice for firefighters

No special advice.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment, see item 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

6.2 Environmental precautions
Due to amount of chemical substances in a mixture, an impact on the environment is not expected.

6.3 Methods and material for containment and cleaning up
Absorb spilled agent with a suitable inert material (sand, earth, vapex) and store contaminated material in containers for collection of hazardous waste. For waste disposal, see Section 13.

6.4 Reference to other sections
See section 7, 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Observe the principles of work in laboratory. Observe the normal operating procedures for handling chemical substances and mixtures. Do not eat, drink or smoke. Use personal protective equipment, see Section 8.

7.2 Conditions for safe storage, including any incompatibilities
Store at a temperature between +2 °C and +8 °C.

7.3 Specific end use(s)
The kit is designed for in vitro diagnostic use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Control parameters are not defined according to Government Decree No 361/2007 Coll. Exposure limit values in the workplace are not defined according to Directive No 2006/15/EC. Limit values for indicators of biological exposure tests are not defined according to Decree No 432/2003 Coll.

8.2 Exposure controls
Appropriate engineering controls
Not required.

Personal protective equipment
a. Eye/face protection
Not required.
b. Hand protection
Not required.
c. Skin protection
Not required.
d. Respiratory protection
Not required.
e. Thermal hazards
None known.

**Environmental exposure controls**
To eliminate the emergency conditions, have pre-prepared a decontamination mixture and appropriate collection vessels for reaction residues. Dispose of reaction residues and decontaminated mixtures as hazardous waste water in accordance with relevant legal regulations.

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

**Reagent 1**

a. Appearance ........................................ Clear colourless liquid
b. Odour ........................................ Information not available
c. Odour threshold ................................ Information not available
d. pH (at 20 °C) ................................ 6.8-7.2

f. Melting point/freezing point ...................... Information not available

h. Initial boiling point and boiling range (°C) Information not available

i. Flash point (°C) ................................ Information not available

j. Upper/lower flammability or explosive limits Information not available

k. Vapour pressure (hPa) .......................... Information not available

l. Vapour density ................................ Information not available

m. Relative density (kg m⁻³)........................ Information not available

n. Water solubility ................................ Soluble

p. Partition coefficient: n-octanol/water ....... Information not available

q. Autoignition temperature (°C)................. Information not available

r. Decomposition temperature (°C)............. Information not available

s. Viscosity ...................................... Information not available

t. Explosive properties ................................ Not explosive

**9.2 Other information**

None.

**SECTION 10: Stability and reactivity**

Under normal conditions of use and storage the mixture is stable.

**10.1 Reactivity**

No data available.

**10.2 Chemical stability**

All components stable when stored in accordance with supplied specifications.

**10.3 Possibility of hazardous reactions**

Not known.

**10.4 Conditions to avoid**

No data available.
10.5 **Incompatible materials**
No data available.

10.6 **Hazardous decomposition products**
No data available.

**SECTION 11: Toxicological information**

a) **Acute toxicity**
Based on available data, the classification criteria are not met.

b) **Irritability**
Based on available data, the classification criteria are not met.

c) **Corrosion**
Based on available data, the classification criteria are not met.

d) **Sensitization**
Based on available data, the classification criteria are not met.

e) **Repeated dose toxicity**
Based on available data, the classification criteria are not met.

f) **Carcinogenicity**
Based on available data, the classification criteria are not met.

g) **Mutagenicity**
Based on available data, the classification criteria are not met.

h) **Reproductive toxicity**
Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information**

12.1 **Toxicity**
The mixture is not classified as toxic to environmental.

12.2 **Persistence and degradability**
No data available.

12.3 **Bioaccumulative potential**
No data available.

12.4 **Mobility in soil**
No data available.

12.5 **Results of PBT and vPvB assessment**
The product does not have the properties of PBT and vPvB. Assessment based on the ingredients that do not have properties of PBT and vPvB.

12.6 **Other adverse effects**
There is no information about any special danger for environment if kit components are handled and disposed of with due care.
SECTION 13: Disposal considerations

13.1 Waste treatment methods
Dispose of in compliance with applicable regulations for hazardous waste management. Do not drain into the wastewater. The mixture should be discarded as a laboratory waste. Incinerate residues of the mixture in a hazardous waste incinerator. Contaminated packaging must be treated as hazardous waste.

SECTION 14: Transport information
Not governed by regulations for transport of dangerous goods (ADR).

14.1 UN number
Not specified.

14.2 UN proper shipping name
ADR/RID: –
IMDG: –
ICAO/IATA: –

14.3 Transport hazard class(es)
ADR/RID: –
IMDG: –
ICAO/IATA: –

14.4 Packing group
ADR/RID: –
IMDG: –
ICAO/IATA: –

14.5 Environmental hazards
The mixture is not hazardous to the environment during transport.

14.6 Special precautions for user
No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not transported.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety data sheet complies with the requirements of Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP).

15.2 Chemical safety assessment
Assessment was not carried out.

SECTION 16: Other information
H-statements: H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
Recommended restrictions on use
This compound is designed for professional use. It should not be used for purposes other than those described in Section 1.2.

Information about data sources used to compile the Safety Data Sheet
Material Safety Data Sheets of raw material suppliers, ECHA (European Chemicals Agency), corporate documentation for products

Added or modified information (compared to the last version of the safety data sheet)
1.1 27.11.2015 Incorporating Commission Regulation (EU) 2015/830

Declaration
The safety data sheet contains basic data corresponding to the present state of our knowledge and experience, in accordance with applicable regulations. The foregoing information was gathered with the utmost care, but that does not mean that it is complete and should be used as the only correct information. Erba Lachema s.r.o. is not responsible for any damages caused by improper use and handling of the mixture.
SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

<table>
<thead>
<tr>
<th>CHOLESTEROL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pack Name</td>
</tr>
<tr>
<td>Cat. No.</td>
</tr>
<tr>
<td>Reagent 2 STD</td>
</tr>
</tbody>
</table>

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

Diagnostic reagent for quantitative in vitro determination of Cholesterol in human serum and plasma.

1.3 Details of the supplier of the safety data sheet

Name of manufacturer: Erba Lachema s.r.o.
Place of business: Brno, Karásek 1d, postcode 621 00, CZ
ID no: 26918846
Phone: +420 517 077 111
E-mail: msds@erbalachema.com

1.4 Emergency telephone number

Erba Lachema s.r.o.
Phone: +420 517 077 556 (service only during business hours)

Toxicological Information Centre (TIS), Na Bojišti 1, 128 01 Prague 2
Phone: +420 224 919 293 or +420 224 915 402 (service available 24 hours a day)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Reagent 2 STD

Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315
Eye Dam. 1 H318

For a full text of H-statements see Section 16.

2.2 Label elements

Reagent 2 STD

Pictogram:

Signal word: Danger

Hazard-determining components of labelling:
Dodecan-1-ol, ethoxylated

Hazard statement(s):
H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statement(s):
P280 Wear protective gloves/protective clothing/eye protection.
2.3 Other hazards
Mixture or components are not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances
The product is a mixture.

3.2 Mixtures
Reagent 2 STD contains following hazardous substances:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Content (% of weight)</th>
<th>CAS number</th>
<th>EC number</th>
<th>Index number</th>
<th>Reg. number</th>
<th>Specific Concentration limits, M-factors</th>
<th>Classification according to 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dodecan-1-ol, ethoxylated</td>
<td>&lt;14</td>
<td>9002-92-0</td>
<td>500-002-6</td>
<td></td>
<td>–</td>
<td>Acute Tox. 4</td>
<td>H302</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit. 2</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1</td>
<td>H318</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>&lt;6.0</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>603-117-00-0</td>
<td>–</td>
<td>Flam. Liq. 2</td>
<td>H225</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1</td>
<td>H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3</td>
<td>H336</td>
</tr>
<tr>
<td>Sodium hydroxide*</td>
<td>&lt;0.2</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>011-002-00-6</td>
<td>–</td>
<td>Skin Corr. 1A; H314: ≥ 5 %</td>
<td>H314</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1B; H314: 2 % ≤ C &lt; 5 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319: 0.5 % ≤ C &lt; 2 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit. 2; H315: 0.5 % ≤ C &lt; 2 %</td>
<td></td>
</tr>
</tbody>
</table>

*) Substance with exposure limits (exposure limits are listed in Section 8.1)
For a full text of H-statements see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures
When working with the mixture, take care of personal hygiene and prevent contamination of work clothing and skin. If you have any doubts or when symptoms persist, seek medical attention.

Exposure by inhalation
Discontinue the exposure, remove casualty to fresh air, keep at rest and seek medical advice.

Exposure by contact with skin
Take off all contaminated clothing. After contact with skin, wash immediately with soap and water.

Exposure by contact with eyes
Rinse an open eye (hold eyelids with fingers) with plenty of water for about 15 minutes, transfer casualty to a specialist.
Exposure by ingestion
Rinse mouth with water, drink 1/2 l of lukewarm water, seek medical attention immediately, do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed
No data available.

4.3 Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5: Firefighting measures
The mixture is not flammable. The measure should be adapted to burning substances in the surrounding area.

5.1 Extinguishing media
Suitable extinguishing media:
Use any extinguishing media appropriate to fire conditions.

5.2 Special hazards arising from the substance or mixture
None known.

5.3 Advice for firefighters
No special advice.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment, see item 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

6.2 Environmental precautions
Due to amount of chemical substances in a mixture, an impact on the environment is not expected.

6.3 Methods and material for containment and cleaning up
Absorb spilled agent with a suitable inert material (sand, earth, vapex) and store contaminated material in containers for collection of hazardous waste. For waste disposal, see Section 13.

6.4 Reference to other sections
See section 7, 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Observe the principles of work in laboratory. Observe the normal operating procedures for handling chemical substances and mixtures. Do not eat, drink or smoke. Use personal protective equipment, see Section 8.

7.2 Conditions for safe storage, including any incompatibilities
Store at a temperature between +2 °C and +8 °C.

7.3 Specific end use(s)
The kit is designed for in vitro diagnostic use.
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Control parameters according to Government Decree No 361/2007 Coll.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance name</th>
<th>PEL</th>
<th>NPK-P</th>
<th>Note</th>
<th>Conversion factor for ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1310-73-2</td>
<td>Sodium hydroxide</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>–</td>
</tr>
</tbody>
</table>

PEL - Permissible exposure limits; NPK-P - the maximum permissible concentration; D - a significant penetration of the substance through the skin or a strong irritating effect on the skin during exposure; S - the substance has a sensitizing effect; P - serious late effects of the substance cannot be excluded; I – causes irritation of mucous membranes (eyes, respiratory system), resp. skin.* - the physico-chemical properties (e.g. explosiveness) are taken into account for NPK-P.

Exposure limit values in the workplace are not defined according to Directive No 2006/15/EC.

Limit values for indicators of biological exposure tests are not defined according to Decree No 432/2003 Coll.

8.2 Exposure controls

Appropriate engineering controls
Not required.

Personal protective equipment
a. Eye/face protection
   Safety goggles.
b. Hand protection
   Protective gloves - rubber, resistant to caustic substances.c. Skin protection
   Protective clothing.
d. Respiratory protection
   Not required.e. Thermal hazards
   None known.

Environmental exposure controls
To eliminate the emergency conditions, have pre-prepared a decontamination mixture and appropriate collection vessels for reaction residues. Dispose of reaction residues and decontaminated mixtures as hazardous waste water in accordance with relevant legal regulations.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Reagent 2 STD
a. Appearance .......................................................... Clear colourless liquid
b. Odour ........................................................................ Odourless
c. Odour threshold .......................................................... Information not available
d. pH (at 20 °C) .......................................................... Information not available
   d. pH (at 20 °C) .......................................................... Information not available
f. Initial boiling point and boiling range (°C) ...................... Information not available
g. Flash point (°C) ...................................................... Incombustible
Name of the mixture: **CHOLESTEROL**

- **h. Evaporation rate**: Information not available
- **i. Flammability (solid, gas)**: Incombustible
- **j. Upper/lower flammability or explosive limits**: Information not available
- **k. Vapour pressure (hPa)**: Information not available
- **l. Vapour density**: Information not available
- **m. Relative density (g cm\(^{-3}\))**: 1.008
- **n. Water solubility**: Soluble
- **o. Partition coefficient: n-octanol/water**: Information not available
- **p. Autoignition temperature (°C)**: Information not available
- **q. Decomposition temperature (°C)**: Information not available
- **r. Viscosity**: Information not available
- **s. Explosive properties**: Not explosive
- **t. Oxidizing properties**: Information not available

### 9.2 Other information

None.

### SECTION 10: Stability and reactivity

Under normal conditions of use and storage the mixture is stable.

#### 10.1 Reactivity

No data available.

#### 10.2 Chemical stability

All components stable when stored in accordance with supplied specifications.

#### 10.3 Possibility of hazardous reactions

Not known.

#### 10.4 Conditions to avoid

Light and heat.

#### 10.5 Incompatible materials

Heavy metals, metal salts, acids.

#### 10.6 Hazardous decomposition products

In case of fire reagent may liberate nitrose gases, carbon monoxide, carbon dioxide.

### SECTION 11: Toxicological information

#### a) Acute toxicity

Based on available data, the classification criteria are not met.

#### b) Irritability

Causes skin irritation.

#### c) Corrosion

Causes serious eye damage.

#### d) Sensitization

Based on available data, the classification criteria are not met.
e) **Repeated dose toxicity**
   Based on available data, the classification criteria are not met.

f) **Carcinogenity**
   Based on available data, the classification criteria are not met.

g) **Mutagenicity**
   Based on available data, the classification criteria are not met.

h) **Reproductive toxicity**
   Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information**

12.1 **Toxicity**
   Do not allow for penetration into waters, sewage or soil.

12.2 **Persistence and degradability**
   No data available.

12.3 **Bioaccumulative potential**
   No data available.

12.4 **Mobility in soil**
   No data available.

12.5 **Results of PBT and vPvB assessment**
   The product does not have the properties of PBT and vPvB. Assessment based on the ingredients that do not have properties of PBT and vPvB.

12.6 **Other adverse effects**
   There is no information about any special danger for environment if kit components are handled and disposed of with due care.

**SECTION 13: Disposal considerations**

13.1 **Waste treatment methods**
   Dispose of in compliance with applicable regulations for hazardous waste management. Do not drain into the wastewater. The mixture should be discarded as a laboratory waste. Incinerate residues of the mixture in a hazardous waste incinerator. Contaminated packaging must be treated as hazardous waste.

   **Waste code**
   15 01 10 packaging containing residues of or contaminated by dangerous substances
   16 05 06 laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals

**SECTION 14: Transport information**

Not governed by regulations for transport of dangerous goods (ADR).

14.1 **UN number**
   Not specified.

14.2 **UN proper shipping name**
   ADR/RID: –
   IMDG: –
Name of the mixture: **CHOLESTEROL**

14.3 Transport hazard class(es)
- ADR/RID: –
- IMDG: –
- ICAO/IATA: –

14.4 Packing group
- ADR/RID: –
- IMDG: –
- ICAO/IATA: –

14.5 Environmental hazards
The mixture is not hazardous to the environment during transport.

14.6 Special precautions for user
No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not transported.

**SECTION 15: Regulatory information**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety data sheet complies with the requirements of Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP).

15.2 Chemical safety assessment
Assessment was not carried out.

**SECTION 16: Other information**

H-statements:  
- H225 Highly flammable liquid and vapour.  
- H302 Harmful if swallowed.  
- H314 Causes severe skin burns and eye damage.  
- H315 Causes skin irritation.  
- H318 Causes serious eye damage.  
- H319 Causes serious eye irritation.  
- H336 May cause drowsiness or dizziness.

**Recommended restrictions on use**
This compound is designed for professional use. It should not be used for purposes other than those described in Section 1.2.

**Information about data sources used to compile the Safety Data Sheet**
Material Safety Data Sheets of raw material suppliers, ECHA (European Chemicals Agency), corporate documentation for products.

**Added or modified information (compared to the last version of the safety data sheet)**
1.1 27.11.2015 Incorporating Commission Regulation (EU) 2015/830
Name of the mixture: **CHOLESTEROL**

**Declaration**

The safety data sheet contains basic data corresponding to the present state of our knowledge and experience, in accordance with applicable regulations. The foregoing information was gathered with the utmost care, but that does not mean that it is complete and should be used as the only correct information. Erba Lachema s.r.o. is not responsible for any damages caused by improper use and handling of the mixture.