Safety Data Sheet

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Name of the mixture: BILIRUBIN TOTAL&DIRECT

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

1.1 Product identifier

<table>
<thead>
<tr>
<th>BILIRUBIN TOTAL&amp;DIRECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pack Name</td>
</tr>
<tr>
<td>Cat. No.</td>
</tr>
<tr>
<td>Reagent 1</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 Total & Direct Bilirubin 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 1
Classification according to Regulation (EC) No 1272/2008
Skin Irrit. 2 H315
Eye Irrit. 2 H319
Classification according to 67/548/EEC or 1999/45/EC
Xi R36/38
For a full text of R-phrases and H-statements see Section 16.

2.2 Label elements

Reagent 1

Pictogram:
Signal word: Warning
Hazard-determining components of labelling: Cetrimonium bromide
Hazard statement(s):
H315 Causes skin irritation.
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Name of the mixture: **BILIRUBIN TOTAL&DIRECT**

H319 Causes serious eye irritation.

Precautionary statement(s):
- P280 Wear protective gloves/protective clothing/eye protection.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 Other hazards
The mixture is 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>Classification according to 67/548/EEC</th>
<th>1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric acid 35–38 %*</td>
<td>&lt;1.2</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>017-002-01-X</td>
<td>C; R34 Xi; R37</td>
<td>Skin Corr. 1B STOT SE 3 H314 H335</td>
</tr>
<tr>
<td>Sulphanilic acid</td>
<td>&lt;0.1</td>
<td>121-57-3</td>
<td>204-482-5</td>
<td>612-014-00-X</td>
<td>Xi; R36/38 R43</td>
<td>Skin Irrit. 2 Skin Sens. 1 Eye Irrit. 2 H315 H317 H319</td>
</tr>
<tr>
<td>Cetrimonium bromide</td>
<td>1.0</td>
<td>1119-97-7</td>
<td>214-291-9</td>
<td></td>
<td>C; R34</td>
<td>Skin. Corr. 1B H314</td>
</tr>
</tbody>
</table>

*) Substance with exposure limits (exposure limits are listed in Section 8.1)
For a full text of R-phrases and 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.

**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.

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
For the mixture no limitations of extinguishing media are given.
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 Section 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 in dry and covered stores in tightly closed containers at a temperature between +2 °C and +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

Control parameters of the mixture components according to Government Decree No 361/2007 Coll.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance name</th>
<th>PEL mg/m³</th>
<th>NPK-P mg/m³</th>
<th>Note</th>
<th>Conversion factor for ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>7647-01-0</td>
<td>Hydrogen chloride</td>
<td>8</td>
<td>15</td>
<td>1</td>
<td>0.679</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 according to Directive No 2006/15/EC.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance name</th>
<th>Limit values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>8 hrs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mg/m³</td>
</tr>
<tr>
<td>7647-01-0</td>
<td>Hydrogen chloride</td>
<td>8</td>
</tr>
</tbody>
</table>

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

Sufficient ventilation.

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 with adequate ventilation, otherwise breathing apparatus.

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

a. Appearance .......................................................... Clear colourless liquid
b. Odour ........................................................................ Information not available
c. Odour threshold ....................................................... Information not available
d. pH (at 20 °C) .............................................................. <2

e. Melting point/freezing point ................................... Information not available
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---

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

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

h. Evaporation rate .......................................................... Information not available

i. Flammability (solid, gas) .................................................. 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 ............................................................... Information not available

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 ....................................................... Information not available

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

The mixture is stable at normal temperature and pressure.

---

10.3 Possibility of hazardous reactions

No data available.

---

10.4 Conditions to avoid

No data available.

---

10.5 Incompatible materials

No data available.

---

10.6 Hazardous decomposition products

Not known.

---

**SECTION 11: Toxicological information**

11.1 Information on toxicological effects

a) Acute toxicity

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

b) Irritability

Irritant effects to eyes and skin.

c) Corrosion

Based on available data, the classification criteria are not met.
**BILIRUBIN TOTAL&DIRECT**

**SECTION 12: Ecological information**

**12.1 Toxicity**
No data available.

**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.

**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: –
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**

**List of H, P-statements and R-phrases**

**H-statements:**  H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

**R-phrases:**  R34 Causes burns.
R36/38 Irritating to eyes and skin.
R37 Irritating to respiratory system.
R43 May cause sensitisation by skin contact.
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

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>Pack Name</th>
<th>BIL T&amp;D 200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat. No.</td>
<td>BLT00011</td>
</tr>
<tr>
<td>Reagent 2</td>
<td>2×50 ml (BID)</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 Total & Direct Bilirubin 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
Classification according to Regulation (EC) No 1272/2008
Mixture is not classified as hazardous.
Classification according to 67/548/EEC or 1999/45/EC
Mixture is not classified as dangerous.

2.2 Label elements

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

2.3 Other hazards

The mixture is not classified as PBT or vPvB.
Reagent 2 contains a small amount of sulphanilic acid. It may cause an allergic skin reaction.

SECTION 3: Composition/information on ingredients

3.1 Substances

The product is a mixture.
3.2 Mixtures
Reagent 2 contains the following hazardous substances:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Content</th>
<th>CAS number</th>
<th>Classification according to 67/548/EEC</th>
<th>1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(% of weight)</td>
<td>EC number</td>
<td>Index number</td>
<td></td>
</tr>
<tr>
<td>Hydrochloric acid 35–38 %*</td>
<td>&lt;1.2</td>
<td>7647-01-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>231-595-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>017-002-01-X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C; R34</td>
<td>Skin Corr. 1B</td>
<td>H314</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Xi; R37</td>
<td>STOT SE 3</td>
<td>H335</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulphanilic acid</td>
<td>0.25</td>
<td>121-57-3</td>
<td>Xi; R36/38</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td>204-482-5</td>
<td>Skin Sens. 1</td>
<td>H317</td>
</tr>
<tr>
<td></td>
<td></td>
<td>612-014-00-X</td>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R43</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*) Substance with exposure limits (exposure limits are listed in Section 8.1)
For a full text of R-phrases and 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. When allergic skin reaction occurs, seek a medical attention.

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
For the mixture no limitations of extinguishing media are given.

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 Section 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

6.2 Environmental precautions
No special precautions required.

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 in dry and covered stores in tightly closed containers at a temperature between +2 °C and +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

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance name</th>
<th>PEL mg/m³</th>
<th>NPK-P mg/m³</th>
<th>Note</th>
<th>Conversion factor for ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>7647-01-0</td>
<td>Hydrogen chloride</td>
<td>8</td>
<td>15</td>
<td>1</td>
<td>0.679</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 according to Directive No 2006/15/EC.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance name</th>
<th>8 hrs Limit values</th>
<th>Short term Limit values</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>7647-01-0</td>
<td>Hydrogen chloride</td>
<td>mg/m³ ppm</td>
<td>mg/m³ ppm</td>
<td>–</td>
</tr>
</tbody>
</table>

The note “skin” attached to the exposure limit values in the workplace indicates the possibility of a serious penetration through the skin.

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
   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

a. Appearance ........................................ Clear colourless liquid

b. Odour ........................................ Information not available

c. Odour threshold .................................. Information not available

d. pH (at 20 °C) ..................................... <2

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

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

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

h. Evaporation rate .................................. Information not available

i. Flammability (solid, gas) ............................. 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 ..................................... Information not available

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 .................................. Information not available

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
The mixture is stable at normal temperature and pressure.

10.3 Possibility of hazardous reactions
No data available.

10.4 Conditions to avoid
No data available.

10.5 Incompatible materials
No data available.

10.6 Hazardous decomposition products
Not known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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
No data available.
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.

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

List of H, P-statements and R-phrases

H-statements:  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.

R-phrases:  
R34 Causes burns.  
R36/38 Irritating to eyes and skin.  
R37 Irritating to respiratory system.  
R43 May cause sensitisation by skin contact.

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

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>Pack Name</th>
<th>BIL T&amp;D 200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat. No.</td>
<td>BLT00011</td>
</tr>
<tr>
<td>Reagent 3</td>
<td>1×6 ml</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 Total & Direct Bilirubin 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 3
Classification according to Regulation (EC) No 1272/2008
Mixture is not classified as hazardous. However, it contains a low concentration of toxic sodium azide with exposure limit.
Classification according to 67/548/EEC or 1999/45/EC
Xn R22

2.2 Label elements

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

2.3 Other hazards

Reagent 3 is not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

The product is a mixture.
3.2 Mixtures
Reagent 3 contains following hazardous substances:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Content (% of weight)</th>
<th>CAS number EC number Index number</th>
<th>Classification according to 67/548/EEC</th>
<th>Classification according to 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium nitrite</td>
<td>1.0</td>
<td>7632-00-0 231-555-9 007-010-00-4</td>
<td>O; R8 T; R25 N; R50</td>
<td>Ox. Sol. 3 Acute Tox. 3 Aquatic Acute 1</td>
</tr>
<tr>
<td>Sodium azide*</td>
<td>&lt;0.1</td>
<td>26628-22-8 247-852-1 011-004-00-7</td>
<td>T+; R28 R32 N; R50-53</td>
<td>Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1</td>
</tr>
</tbody>
</table>

*) Substance with exposure limits (exposure limits are listed in Section 8.1)
For a full text of R-phrases and 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. Consult a physician.

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
For the mixture no limitations of extinguishing media are given.

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 Section 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

6.2 Environmental precautions
Do not discharge into the drains, surface waters and groundwater.

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 in dry and covered stores in tightly closed containers at a temperature between +2 °C and +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

Control parameters of the mixture components according to Government Decree No 361/2007 Coll.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance name</th>
<th>PEL mg/m³</th>
<th>NPK-P mg/m³</th>
<th>Note</th>
<th>Conversion factor for ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>26628-22-8</td>
<td>Sodium azide</td>
<td>0.1</td>
<td>0.3</td>
<td>D, I</td>
<td>0.376</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 according to Directive No 2006/15/EC.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance name</th>
<th>Limit values</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>8 hrs</td>
<td>Short term</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mg/m³ ppm</td>
<td>mg/m³ ppm</td>
</tr>
<tr>
<td>26628-22-8</td>
<td>Sodium azide</td>
<td>0.1 – – 0.3</td>
<td>Skin</td>
</tr>
</tbody>
</table>

The note “skin” attached to the exposure limit values in the workplace indicates the possibility of a serious penetration through the skin.

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
a. Appearance .......................................................... Clear colourless liquid
b. Odour .......................................................... Information not available
c. Odour threshold .............................................. Information not available
d. pH (at 20 °C) .................................................. 6–8
e. Melting point/freezing point .......................... Information not available
f. Initial boiling point and boiling range (°C) .... Information not available
g. Flash point (°C) ........................................ Information not available
h. Evaporation rate .......................................... Information not available
i. Flammability (solid, gas) ............................ 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 ............................................. Information not available
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 .................................... Information not available
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
The mixture is stable at normal temperature and pressure.

10.3 Possibility of hazardous reactions
Not known.

10.4 Conditions to avoid
No data available.

10.5 Incompatible materials
Acids.

10.6 Hazardous decomposition products
No dangerous decomposition products known.

SECTION 11: Toxicological information
11.1 Information on toxicological effects
   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
No data available.

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.

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

List of H and R-phrases

H-statements:
- H272 May intensify fire; oxidizer.
- H300 Fatal if swallowed.
- H301 Toxic if swallowed.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

R-phrases:
- R8 Contact with combustible material may cause fire.
- R25 Toxic if swallowed.
- R32 Contact with acids liberates very toxic gas.
- R50 Very toxic to aquatic organisms.
- R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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.

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.