Safety Data Sheet

Date of issue: 1.2. 2013 Date of review: Page 1 of 9 pages Version: 1

Name of the mixture: BILIRUBIN DIRECT

1 Identification of the substance/mixture and company/undertaking

1.1 Product identifier

<table>
<thead>
<tr>
<th>BILIRUBIN DIRECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
</tr>
<tr>
<td>Catalog Number</td>
</tr>
<tr>
<td>Reagent 1</td>
</tr>
<tr>
<td>Reagent 2</td>
</tr>
</tbody>
</table>

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

The sets are designed for Health Service laboratories for determination of bilirubin direct concentration in serum and plasma. The mixture is intended for professional use.

1.3 Details of the supplier of the safety data sheet

Name or trade name of manufacturer: Erba Lachema s.r.o.
Place of business: Brno, Karásek 1d, postcode 621 00
ID no.: 26918846
Phone: +420 517 077 579
Fax: +420 517 077 077
Qualified person: Ing. Pavel Filka
E-mail: filka@erbalachema.com
Phone: +420 517 077 556

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)
Safety Data Sheet

Date of issue: 1.2. 2013  Date of review:  
Name of the mixture: BILIRUBIN DIRECT

2 Hazards Identification
2.1 Classification of the mixture
The kit Bilirubine direct is not classified as dangerous according to EU Directives 1999/45/EC as amended

2.2 Label elements
none

3 Composition/information on ingredients
3.1 Composition

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Content (% of weight)</th>
<th>CAS number</th>
<th>EC number</th>
<th>Classification according to (EC) No. 67/548 EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric acid</td>
<td>&lt; 0.5</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C; R: 34-37; S: 26-45</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1B; STOT SE 3; H314; H335; P261, P280, P305+P351+P338, P310</td>
</tr>
<tr>
<td>Sulphanilic acid</td>
<td>&lt; 0.5</td>
<td>121-57-3</td>
<td>204-482-5</td>
<td>Xi; R36/38 - R43; S 24-37</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; Skin Irrit. 2; Skin Sens. 1; H319, H315, H317; P280, P305+P351+P338</td>
</tr>
</tbody>
</table>

*) Substance with exposure limits (exposure limits are listed in Chapter 8.1)
For a full text of R-phrases, S-phrases, H-phrases and P-phrases see Section 16.

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
None

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

5 Fire-fighting measures

5.1 Extinguishing media
Suitable extinguishing media
The mixture is not flammable, the measure should be adapted to burning substances in the surrounding area.

Unsuitable extinguishing media
None known.

5.2 Special hazards arising from the substance or mixture
None

5.3 Advice for firefighters
Protective clothing, breathing apparatus.

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
Do not discharge into the drains, surface waters, 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 item 13.
Sweep solid reagent and store in containers for collection of hazardous waste. For waste disposal see item 13.

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 item 8.

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

7.3 Specific end use
The kit is designed for in vitro diagnostic devices.
8 Exposure controls/personal protection

8.1 Exposure limit values

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</th>
<th>NPK-P</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  mg/m³</td>
<td>15 mg/m³</td>
<td></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; * - 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 Long time</td>
<td>Short time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mg/m³ ppm</td>
<td>mg/m³ ppm</td>
</tr>
<tr>
<td>7647-01-0</td>
<td>Hydrogen chloride</td>
<td>8  5 ppm 15 ppm 10 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 in urine for the product according to Decree No. 432/2003 Coll.
No data Available

8.2 Exposure controls

8.2.1 Appropriate engineering controls
None

8.2.2 Personal protective equipment
A) Respiratory protection: Not required with adequate ventilation, otherwise breathing apparatus.
B) Hand protection: Protective gloves - rubber, resistant to caustic substances.
C) Eye protection: Safety goggles.
D) Skin protection: Protective clothing.

8.2.3 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.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Reagent 1
a. Appearance................................. Clear colorless liquid
b. Odour.................................... no data available
c. Odour Threshold........................ no data available
d. pH (pH 20°C)............................. <2
e. Melting point / freezing point........ no data available
f. Initial boiling point and boiling range (°C) no data available
g. Flash point (°C)........................ no data available
h. Evaporation rate........................ no data available
i. Flammability (solid, gas)................................. no data available
j. Upper/lower flammability or explosive limits ........... no data available
k. Vapour pressure (hPa)................................. no data available
l. Vapour density ............................................. no data available
m. Relative density (kg.m-3)............................... no data available
n. Water solubility .......................................... no data available
o. Partition coefficient: n- octanol/water ................. no data available
p. Autoignition temperature (°C) ......................... no data available
q. Decomposition temperature (°C) ...................... no data available
r. Viscosity ..................................................... no data available
s. Explosive properties ..................................... no data available
t. Oxidizing properties ..................................... no data available

Standard (Calibrator)

a. Appearance ................................................. Clear colorless liquid
b. Odour ........................................................ no data available
c. Odour Threshold .......................................... 6.0 – 8.0
d. pH (pH 20°C) ................................................. no data available
e. Melting point / freezing point ............................... no data available
f. Initial boiling point and boiling range (°C) ............... no data available
g. Flash point (°C) .............................................. no data available
h. Evaporation rate ............................................. no data available
i. Flammability (solid, gas)................................. no data available
j. Upper/lower flammability or explosive limits ........... no data available
k. Vapour pressure (hPa)................................. no data available
l. Vapour density ............................................. no data available
m. Relative density (kg.m-3)............................... no data available
n. Water solubility .......................................... no data available
o. Partition coefficient: n- octanol/water ................. no data available
p. Autoignition temperature (°C) ......................... no data available
q. Decomposition temperature (°C) ...................... no data available
r. Viscosity ..................................................... no data available
s. Explosive properties ..................................... no data available
t. Oxidizing properties ..................................... no data available

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
No data available

10.3 Possibility of hazardous reactions
No data available

10.4 Conditions to avoid
Avoid exposure to heat of solar radiation
Name of the mixture: BILIRUBIN DIRECT

10.5 Incompatible material
    Heavy Metals, strong oxidizing agents and strong acids

10.6 Hazardous decomposition products
    Nitrogen oxide and carbon

11 Toxicological information

11.1 Acute toxicity
    Human oral LD₅₀ (g.kg⁻¹) ...................... not applicable
    Rat oral LD₅₀ (g.kg⁻¹) .......................... not applicable
    Rat inhalation LD₅₀ (g.kg⁻¹) .................. not applicable
    Rat inhalation TLS (g.kg⁻¹) .................... not applicable

11.2 Skin corrosion/irritation
    Not applicable.

11.3 Serious eye damage/eye irritation
    Not applicable.

11.4 Respiratory or skin sensitization
    Not applicable.

11.5 Germ cell mutagenicity
    Not applicable.

11.6 Carcinogenicity
    Not applicable.

11.7 Reproductive toxicity
    Not applicable.

11.8 Specific target organ toxicity - single exposure
    Not applicable.

11.9 Specific target organ toxicity - repeated exposure
    Not applicable.

11.10 Aspiration hazard
    Not applicable.

12 Ecological information

12.1 Ecotoxicity
    Waste water
    LC₅₀ 96 hrs, fish (mg.kg⁻¹) .................... not applicable
    EC₅₀ 48 hrs, daphnia (mg.kg⁻¹) ............... not applicable
    IC₅₀ 72 hrs algae (mg.kg⁻¹) ................... not applicable
    CHSK ........................................ not applicable
    BSK ............................................ not applicable

12.2 Persistence and degradability
    Not applicable.
12.3 Bioaccumulative potential
Not applicable.

12.4 Mobility in soil
Not applicable.

12.5 Results of PBT and vPvB assessment
Not applicable.

12.6 Other adverse effects
Not applicable.

13 Disposal considerations

13.1 Waste treatment methods
Dispose of in compliance with applicable regulations for hazardous waste management. Incinerate residues of the mixture in a hazardous waste incinerator. Contaminated packaging must be treated as hazardous waste. Dispose of by incinerating in a hazardous waste incinerator.

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

14.1 UN number
ADR/RID:
IMDG:
IATA:

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

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

14.4 Packaging group
ADR/RID:
IMDG:
IATA:

14.5 Environmental hazards
ADR/RID:
IMDG:
IATA:

14.6 Special precautions for user
No data available

15 Regulatory Information
This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
no data available

15.2 Chemical Safety
no data available

16 Further information

List of R-phrases
R 36/38 Irritating to eyes and skin.
R 43 May cause sensitization by skin contact.
R 28 Very toxic if swallowed.
R 32 Contact with acids liberates very toxic gas.
R 50/53 Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.
R 34 Causes burns.
R 37 Irritating to respiratory system.

List of H-phrases:
H314 Causes severe skin burns and eye damage.
H335 May cause respiratory irritation.
H300 Fatal if swallowed.
H410 Very toxic to aquatic life with long lasting effects.
H319 Causes serious eye irritation.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H272 May intensify fire; oxidiser.
H301 Toxic if swallowed.
H400 Very toxic to aquatic life.

List of P-phrases:
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P501 Dispose of contents/container to an approved waste disposal plant.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P301 If swallowed.
P310 Immediately call a POISON CENTER or doctor/physician.
P220 Keep/Store away from clothing/…/combustible materials.

List of S-phrases:
S 24 Avoid contact with skin.
S 37 Wear suitable gloves.
S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 36 Wear suitable protective clothing.
S 46 If swallowed, seek medical advice immediately and show this container or label.
S 61 Avoid release to the environment. Refer to special instructions/ Safety data sheets.
S 28 After contact with skin, wash immediately with plenty of soap and water.
S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S 60 This material and its container must be disposed of as hazardous waste.
Training instructions
Workers who come into contact with hazardous materials shall be acquainted by the organization, to a necessary extent, with the effects of these substances, with the methods how to treat them, with protective measures, the principles of first aid, necessary sanitation procedures and procedures for liquidation of failures and accidents. Under Article 35 of the European Parliament and Council Regulation (EC) No. 1907/2006, the employer must enable employees or their representatives access to information from the safety data sheet of the substance or mixture the worker uses or the effects of which can be exposed to during his/her work.

Recommended restrictions on use
The mixture is intended for professional use. It should not be used for purposes other than those listed under 1.2.

Further information
Information given is based on our best knowledge and is intended to describe the product for the purposes of safety of transporting and handling only. It should not be therefore construed as guaranteeing any specific property of the product. It is the responsibility of the user to observe all current regulations and consider recommendations on the use of application of product.

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.