

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 1 of 10 pages

Version: 1

Name of the mixture: **BILIRUBIN DIRECT**

1 Identification of the substance/mixture and company/undertaking

1.1 Product identifier

BILIRUBIN DIRECT	
Product Name	BIL D 200
Catalog Number	BLT00009
Reagent 1	4 x 50 ml
Reagent 2	1 x 6 ml

1.2 Use of the substance or mixture

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 Company/undertaking identification

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

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013	Date of review:	Page 2 of 10 pages	Version: 1
--------------------------	-----------------	--------------------	------------

Name of the mixture: **BILIRUBIN DIRECT**

2 Hazards Identification

2.1 Classification of the mixture

Reagent 2

The reagent 2 of the kit **Bilirubine direct** is classified as dangerous according to EU Directives 1999/45/EC as amended

Xn, Harmful; R 22 Harmful if swallowed.

2.2 Label elements

Xn



Symbols:

Harmful

Risk phrases (R):

R 22 Harmful if swallowed

Safety phrases (S):

S 29 Do not empty into drains

S 36 Wear suitable protective clothing.

S 46 If swallowed seek medical advice immediately and show this container or label

3 Composition/information on ingredients

3.1 Composition

The reagent 1 contains the following hazardous substances:

Substance name	Content (% of weight)	CAS number	EC number	Classification according to (EC) No. 67/548 EEC
				Classification according to (EC) No. 1272/2008
Hydrochloric acid 37% or 32%*	< 1	7647-01-0	231-595-7	C; R: 34-37; S: 26-45
				Skin Corr. 1B; STOT SE 3; H314, H335; P261, P280, P305+P351+P338, P310
Sulphanilic acid	< 0.3	121-57-3	204-482-5	Xi; R36/38 - R43; S 24-37
				Eye Irrit. 2; Skin Irrit. 2; Skin Sens. 1; H319, H315, H317; P280, P305+P351+P338

The reagent 2 contains the following hazardous substances:

Substance name	Content (% of weight)	CAS number	EC number	Classification according to (EC) No. 67/548 EEC
				Classification according (EC) No. 1272/2008
Sodium nitrite	1	7632-00-0	231-555-9	T, O, N; R 8-25-50; S: 45-61;
				Ox. Sol. 3, Acute Tox. 3, Aquatic Acute 1 H272, H301, H400; P220, P273, P301+P310
Sodium azide*	< 0.1	26628-22-8	247-852-1;	T+; N; R 28-32-50/53; S 28-45-60-61

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 3 of 10 pages

Version: 1

Name of the mixture: **BILIRUBIN DIRECT**

Acute Tox. 1, Aquatic Acute 1, Aquatic Chronic 1; H300, H400, H410; P273, P501, EUH032

*) 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.

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013	Date of review:	Page 4 of 10 pages	Version: 1
--------------------------	-----------------	--------------------	------------

Name of the mixture: **BILIRUBIN DIRECT**

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.

CAS	Substance name	PEL	NPK-P	Note	Conversion factor for ppm
		mg/m ³	mg/m ³		
26628-22-8	Sodium azide	0.1	0.3	D	0.376
7647-01-0	Hydrogen chloride	8	15		0.679

*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

CAS	Substance name	Limit values				Note
		8 hrs		Short time		
		mg/m ³	ppm	mg/m ³	ppm	
26628-22-8	Sodium azide	0.1	-	0.3	-	skin
7647-01-0	Hydrogen chloride	8	5	15	10	-

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

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 5 of 10 pages

Version: 1

Name of the mixture: **BILIRUBIN DIRECT**

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 liquide
- b. Odour..... no data available
- c. Odour Threshold no data available
- d. pH (při 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 liquide
- b. Odour..... no data available
- c. Odour Threshold 6.0 – 8.0
- d. pH (při 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

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 6 of 10 pages

Version: 1

Name of the mixture: **BILIRUBIN DIRECT**

- 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

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.

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 7 of 10 pages

Version: 1

Name of the mixture: **BILIRUBIN DIRECT**

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

BSK₅ 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:

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 8 of 10 pages

Version: 1

Name of the mixture: **BILIRUBIN DIRECT**

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 8 Contact with combustible material may cause fire.

R 22 Harmful if swallowed

R 25 Toxic if swallowed.

R 50 Very toxic to aquatic organisms.

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.

H272 May intensify fire; oxidiser.

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 9 of 10 pages

Version: 1

Name of the mixture: **BILIRUBIN DIRECT**

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 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.

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 10 of 10 pages

Version: 1

Name of the mixture: **BILIRUBIN DIRECT**