

**BILIRUBIN TOTAL&DIRECT\_R1**

Creation date	25th May 2015	Version	4.0
Revision date	06th February 2024		

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

Substance / mixture	BILIRUBIN TOTAL&DIRECT_R1
Number	mixture
UFI	BLT00011
Other mixture names	OV0F-WE2R-2H7R-9P9K
	BIL T&D 200

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Mixture's intended use**

Diagnostic reagent for quantitative in vitro determination of Total & Direct Bilirubin in human serum and plasma.

**Main intended use**

PC-MED-OTH Other medical devices

**Secondary uses**

PC-TEC-19 Reagents and laboratory chemicals

**Mixture uses advised against**

not available

**1.3. Details of the supplier of the safety data sheet****Manufacturer**

Name or trade name	Erba Lachema s.r.o.
Address	Karásek 2219/1d , Brno, 62100
	Czech Republic
Identification number (CRN)	26918846
VAT Reg No	CZ26918846
Phone	+420 517 077 111
E-mail	msds@erba.com
Web address	www.erbalachema.com

**Competent person responsible for the safety data sheet**

Name	Erba Lachema s.r.o.
E-mail	msds@erba.com

**1.4. Emergency telephone number**

European emergency number: 112 112

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification of the mixture in accordance with Regulation (EC) No 1272/2008**

The mixture is classified as dangerous.

Skin Corr. 1, H314

Eye Dam. 1, H318

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

Causes severe skin burns and eye damage.

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

Danger

**Hazard statements**

H314 Causes severe skin burns and eye damage.

**Precautionary statements**

P260 Do not breathe vapours.

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P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**Supplemental information**

EUH208 Contains sulphanilic acid. May produce an allergic reaction.

**2.3. Other hazards**

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Mixture of substances and additives specified below.

**Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment**

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 1119-97-7 EC: 214-291-9	Tetradonium bromide	<2,5	Skin Corr. 1C, H314	
Index: 017-002-01-X CAS: 7647-01-0 EC: 231-595-7	Hydrochloric acid 35%	<0,6	Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335 Specific concentration limit: Skin Corr. 1B, H314: C ≥ 25 % Skin Irrit. 2, H315; Eye Irrit. 2, H319: 10 % ≤ C < 25 % STOT SE 3, H335: C ≥ 10 %	1
Index: 612-014-00-X CAS: 121-57-3 EC: 204-482-5	sulphanilic acid	<0,5	Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319	

**Notes**

1 A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures**

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

**If inhaled**

Take care of your own safety, do not let the affected person walk! Terminate the exposure immediately; move the affected person to fresh air. Beware of the contaminated clothes. Depending on the situation, call the medical rescue service and ensure medical treatment considering the frequent need of further observation for at least 24 hours.

**If on skin**

Remove contaminated clothes. Take off any rings, watches, bracelets before or during washing if worn in the contaminated areas of the skin. Depending on the situation, call the medical rescue service and always ensure medical treatment. Rinse contaminated areas with a flow of water, lukewarm at best, for 10-30 minutes; do not use any brush, soap or neutralizers. Rinse skin with water or shower. Rinse cautiously with water for several minutes.

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**If in eyes**

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. No neutralization should be performed in any case! Rinsing should be continued for 10-30 minutes from the inner to the outer eye corner to make sure that the other eye is not involved. Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible. Everyone must be referred for treatment even if affected only a little.

**If swallowed**

Danger of esophageal and gastric perforation! RINSE THE MOUTH WITH WATER IMMEDIATELY AND LET THE PERSON DRINK 2-5 dl of cold water to reduce the heating effect of the corrosive substance. Consuming larger amounts of liquid is not advisable as it may induce vomiting and potential inhaling of the corrosive substances in the lungs. The affected person must not be forced to drink, particularly if already feeling pain in the mouth or throat. In this case let the affected person only rinse the mouth with water. DO NOT PROVIDE ACTIVATED CARBON! Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible.

**4.2. Most important symptoms and effects, both acute and delayed****If inhaled**

Inhaling vapours can cause corrosion of the breathing system.

**If on skin**

Causes severe skin burns.

**If in eyes**

Causes serious eye damage.

**If swallowed**

Corrosion of the digestion system can occur.

**4.3. Indication of any immediate medical attention and special treatment needed**

Symptomatic treatment.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

Accommodate extinguishing components to the location of fire. Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

**Unsuitable extinguishing media**

Water - full jet.

**5.2. Special hazards arising from the substance or mixture**

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

**5.3. Advice for firefighters**

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

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Observe the principles of work safety in chemical laboratories. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale aerosols. Prevent contact with skin and eyes.

**6.2. Environmental precautions**

Prevent contamination of the soil and entering surface or ground water.

**6.3. Methods and material for containment and cleaning up**

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

**6.4. Reference to other sections**

See the Section 7, 8 and 13.

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

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Do not inhale aerosols. Prevent contact with skin and eyes. Wash hands and exposed parts of the body thoroughly after handling. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Observe the principles of safety work in chemical laboratories.

**7.2. Conditions for safe storage, including any incompatibilities**

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose. Store locked up.

Storage temperature min 2 °C, max 8 °C

**7.3. Specific end use(s)**

not available

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

The mixture contains substances for which occupational exposure limits are set.

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

Substance name (component)	Type	Value	Note
Hydrochloric acid 35% (CAS: 7647-01-0)	PEL	8 mg/m <sup>3</sup>	irritating to mucous membranes (eyes, respiratory system) and skin
	PEL	5 ppm	
	NPK-P	15 mg/m <sup>3</sup>	
	NPK-P	10 ppm	

**European Union****Commission Directive 2000/39/EC**

Substance name (component)	Type	Value	Note
Hydrochloric acid 35% (CAS: 7647-01-0)	OEL 8 hours	8 mg/m <sup>3</sup>	
	OEL 8 hours	5 ppm	
	OEL 15 minutes	15 mg/m <sup>3</sup>	
	OEL 15 minutes	10 ppm	

**8.2. Exposure controls**

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

**Eye/face protection**

Protective goggles or face shield (based on the nature of the work performed).

**Skin protection**

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

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**Respiratory protection**

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

**Thermal hazard**

Not available.

**Environmental exposure controls**

Observe usual measures for protection of the environment, see Section 6.2.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state	liquid
Colour	colourless
Odour	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	The product is non-flammable.
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	<2 (undiluted)
Kinematic viscosity	data not available
Solubility in water	data not available
Solubility in fats	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available
Form	Clear colourless liquid

**9.2. Other information**

Evaporation rate	data not available
Oxidising properties	The product has no oxidizing properties.
Explosive properties	The product does not have explosive properties.

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

not available

**10.2. Chemical stability**

The product is stable under normal conditions.

**10.3. Possibility of hazardous reactions**

Unknown.

**10.4. Conditions to avoid**

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

**10.5. Incompatible materials**

Protect against strong acids, bases and oxidizing agents.

**10.6. Hazardous decomposition products**

Not developed under normal uses.

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**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

**Acute toxicity**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Skin corrosion/irritation**

Causes severe skin burns and eye damage. Data for the components of the mixture are not available.

**Serious eye damage/irritation**

Causes severe skin burns and eye damage. Causes serious eye damage. Data for the components of the mixture are not available.

**Respiratory or skin sensitisation**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Germ cell mutagenicity**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Carcinogenicity**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Reproductive toxicity**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Toxicity for specific target organ - single exposure**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Toxicity for specific target organ - repeated exposure**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**Aspiration hazard**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

**11.2. Information on other hazards**

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

**SECTION 12: Ecological information****12.1. Toxicity**

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

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**Acute toxicity**

Hydrochloric acid 35%				
Parameter	Value	Exposure time	Species	Environment
LC <sub>50</sub>	20.5 mg/l	96 hours	Fish	

**12.2. Persistence and degradability**

No data are available for either the mixture or the components.

**12.3. Bioaccumulative potential**

No data are available for either the mixture or the components.

**12.4. Mobility in soil**

No data are available for either the mixture or the components.

**12.5. Results of PBT and vPvB assessment**

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

**12.6. Endocrine disrupting properties**

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

**12.7. Other adverse effects**

Not available.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

**Waste management legislation**

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

**Waste type code**

16 05 06\* laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals

**Packaging waste type code**

15 01 10\* packaging containing residues of or contaminated by hazardous substances

(\*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

**SECTION 14: Transport information****14.1. UN number or ID number**

not subject to transport regulations

**14.2. UN proper shipping name**

not relevant

**14.3. Transport hazard class(es)**

not relevant

**14.4. Packing group**

not relevant

**14.5. Environmental hazards**

not relevant

**14.6. Special precautions for user**

Reference in the Sections 4 to 8.

**14.7. Maritime transport in bulk according to IMO instruments**

not relevant

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**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006, as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

**15.2. Chemical safety assessment**

not available

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

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

**Guidelines for safe handling used in the safety data sheet**

P260	Do not breathe vapours.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

EUH208	Contains sulphanilic acid. May produce an allergic reaction.
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**Other important information about human health protection**

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

**Key to abbreviations and acronyms used in the safety data sheet**

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization



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IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC <sub>50</sub>	Lethal concentration of a substance in which it can be expected death of 50% of the population
log K <sub>ow</sub>	Octanol-water partition coefficient
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
Eye Dam.	Serious eye damage
Met. Corr.	Corrosive to metals
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization
STOT SE	Specific target organ toxicity - single exposure

**Training guidelines**

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

**Recommended restrictions of use**

not available

**Information about data sources used to compile the Safety Data Sheet**

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.  
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

**The changes (which information has been added, deleted or modified)**

The version 4.0 replaces the SDS version from 02 July 2021. Changes were made in sections 2, 11, 12, 15 and 16.

**More information**

Classification procedure - calculation method.

**Statement**

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.