

**BIL D DCA 500\_R1**

Creation date	28th May 2015		
Revision date	29th January 2024	Version	4.0

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

Substance / mixture	BIL D DCA 500_R1
Number	mixture
UFI	BLT00078
Other mixture names	3Y1V-UW5E-7J56-T02F
	BILIRUBIN DIRECT DCA

**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 Bilirubin Direct in human serum and plasma.

**Main intended use**

PC-MED-OTH	Other medical devices
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**Secondary uses**

PC-TEC-19	Reagents and laboratory chemicals
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**The use descriptors**

PC 21	Laboratory chemicals
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**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.

Met. Corr. 1, H290

Skin Corr. 1, H314

Eye Dam. 1, H318

**Most serious adverse physico-chemical effects**

May be corrosive to metals.

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

Causes severe skin burns and eye damage.

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## 2.2. Label elements

## Hazard pictogram



## Signal word

Danger

## Hazard statements

H290 May be corrosive to metals.  
H314 Causes severe skin burns and eye damage.

## Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection.  
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.  
P390 Absorb spillage to prevent material damage.

## 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
Index: 016-026-00-0 CAS: 5329-14-6 EC: 226-218-8	sulphamidic acid	<1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 3, H412	

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/shower. Rinse cautiously with water for several minutes. Cover with sterile dressing material to protect against infection.

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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**

DO NOT INDUCE VOMITING - there is danger of further damage to the gastrointestinal tract!!! 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.

**More information**

A corrosive effect cannot be ruled out because of the pH value.

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

The product is non-flammable. Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist. Use suitable extinguishing media according burning substances of surroundings.

**Unsuitable extinguishing media**

Water - full jet.

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

Fires in the immediate vicinity may cause the development of dangerous vapours. In case of fire may be liberated: sulphur oxides, nitrogen oxides (NOx).

**5.3. Advice for firefighters**

In case of surrounding fires: Wear self-contained breathing apparatus. Hazchem-Code: 2X. 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**

May be corrosive to metals. Ensure good ventilation. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale vapours. 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. Absorb spillage to prevent material damage.

**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**

Do not inhale vapours. Provide adequate ventilation, and local exhaust as needed. 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. Do not eat, drink or smoke when using this product. Take off immediately all contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

**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. Do not expose to sunlight. Store locked up. Store only in the original package. Do not freeze. Protect from light. Keep sterile.

Storage class 8B - Non-combustible corrosive substances

Storage temperature min 2 °C, max 8 °C

**The specific requirements or rules relating to the substance/mixture**

Unsuitable materials: Metals.

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

The reagent of the kit is designed for in vitro diagnostic use.

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

none

**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**

Safety glasses according to EN 166 or a face shield (depending on the nature of the work performed).

**Skin protection**

Hand protection: Protective gloves resistant to the product according to EN 374. Glove material: Nitrile rubber-Layer thickness: 0.11 mm. Breakthrough time: >480 min. 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.

**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	odourless without fragrance
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	1.1 (undiluted at 25 °C)
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

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Vapour pressure	data not available
Density and/or relative density	
Density	1.0103 g/cm <sup>3</sup> at 20 °C
Relative vapour density	data not available
Particle characteristics	data not available
Form	Clear colourless liquid

**9.2. Other information**

Evaporation rate	data not available
Explosive properties	The product does not have explosive properties.

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

May be corrosive to metals.

**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 from alkalis and metals.

**10.6. Hazardous decomposition products**

In case of fire may be liberated: Sulphur oxides, nitrogen oxides (NO<sub>x</sub>).

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

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.

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**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**

Harmful effects on water organisms by modification of pH-value.

**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**

Not available.

**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

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

UN 3264

**14.2. UN proper shipping name**

CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Sulphamidic acid mixture)

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

8 Corrosive substances

**14.4. Packing group**

III

**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

**Additional information**

Hazard identification No.

**80**

UN number

**3264**

Classification code

C1

Safety signs

8



Tunnel restriction code

(E)

**Air transport - ICAO/IATA**

Packaging instructions passenger

852

Cargo packaging instructions

856

**Marine transport - IMDG**

EmS (emergency plan)

F-A, S-B

**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.

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- H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H412 Harmful to aquatic life with long lasting effects.

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

- P280 Wear protective gloves/protective clothing/eye protection.  
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.  
P390 Absorb spillage to prevent material damage.

**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  
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  
log Kow Octanol-water partition coefficient  
OEL Occupational Exposure Limits  
PBT Persistent, Bioaccumulative and Toxic  
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

- Aquatic Chronic Hazardous to the aquatic environment (chronic)  
Eye Dam. Serious eye damage  
Met. Corr. Corrosive to metals  
Skin Corr. Skin corrosion

**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



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**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 11 October 2022. Changes were made in sections 2, 11, 15 and 16.

**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.