

BIL D DCA 500_R1

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

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

- 1.1. Product identifier**
Substance / mixture BIL D DCA 500_R1
mixture
Number BLT00078
UFI 3Y1V-UW5E-7J56-T02F
Other mixture names
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
Secondary uses
PC-TEC-19 Reagents and laboratory chemicals
The use descriptors
PC 21 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.
- 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.

BIL D DCA 500_R1

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

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.

BIL D DCA 500_R1

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

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 (NO_x).

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.

BIL D DCA 500_R1

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

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

BIL D DCA 500_R1

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

Vapour pressure	data not available
Density and/or relative density	
Density	1.0103 g/cm ³ 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_x).

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.

BIL D DCA 500_R1

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

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

BIL D DCA 500_R1

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

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.

BIL D DCA 500_R1

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

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 K _{ow}	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

BIL D DCA 500_R1

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

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.