



20.01.2025

Kit Components

Product code	Description
--------------	-------------

427	Bilirubina Diretta / Direct Bilirubin B81180031 - B81180032 - B75182500 - B74182700 - B74182745
------------	--

Components:

291105	Bilirubina Diretta - Acido Solfanilico
291083	Bilirubina Diretta - Sodio Nitrito

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Bilirubina Diretta - Acido Solfanilico
- **Article number:** 291105
- **CAS Number:**
7732-18-5
- **EC number:**
231-791-2
- **UFI:** 1500-XOUR-Y000-Y03U
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
Relevant Identified Uses: For laboratory use only
Uses advised against: Uses other than those recommended
- **Application of the substance / the mixture** Diagnostic reagent
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Sclavo Diagnostics International
Via Po 26-28, Loc. Pian dei Mori
CAP: 53018 - SOVICILLE - (SI)
ITALY
- **Further information obtainable from:** Product safety department.
- **1.4 Emergency telephone number:** +39 0577 390 444 / 445

2 Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS05 corrosion

Skin Corr. 1 H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS05

(Contd. on page 2)

IE

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Acido Solfanilico

(Contd. of page 1)

- **Signal word** *Danger*
- **Hazard statements**
H314 Causes severe skin burns and eye damage.
- **Precautionary statements**
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.
P310 Immediately call a POISON CENTER/doctor.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**
Contains sulphanilic acid. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**
7732-18-5 water, distilled, conductivity or of similar purity
- **Identification number(s)**
- **EC number:** *231-791-2*

• **Dangerous components:**

CAS: 121-57-3	sulphanilic acid	≥0.25-<1%
EINECS: 204-482-5	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

4 First aid measures

- **4.1 Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
- **After inhalation:**
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Drink plenty of water and provide fresh air. Call for a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.

(Contd. on page 3)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Acido Solfanilico

(Contd. of page 2)

- **4.3 Indication of any immediate medical attention and special treatment needed**
 No further relevant information available.

5 Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
 Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
 During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
 Mount respiratory protective device.
 Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Dilute with plenty of water.
- **6.3 Methods and material for containment and cleaning up:**
 Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
 Use neutralising agent.
 Dispose contaminated material as waste according to section 13.
 Ensure adequate ventilation.
- **6.4 Reference to other sections**
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.
 See Section 13 for disposal information.

7 Handling and storage

- **7.1 Precautions for safe handling**
 Ensure good ventilation/exhaustion at the workplace.
 Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
 Keep respiratory protective device available.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
 No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
 Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
 Not required.

(Contd. on page 4)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Acido Solfanilico

(Contd. of page 3)

- **Additional information:**
The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Hand protection**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection**



Tightly sealed goggles

9 Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Liquid
- **Colour:** Colourless
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C (7732-18-5 water, distilled, conductivity or of similar purity)
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.

(Contd. on page 5)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Acido Solfanilico

(Contd. of page 4)

• Upper:	Not determined.
• Flash point:	Not applicable.
• Decomposition temperature:	Not determined.
• pH	pH below -3.
• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic at 20 °C:	0.952 mPas
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Density and/or relative density	
• Density at 20 °C:	1.00482 g/cm ³
• Relative density	Not determined.
• Vapour density	Not determined.
• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• Important information on protection of health and environment, and on safety.	
• Ignition temperature:	Not determined.
• Explosive properties:	Product does not present an explosion hazard.
• Solvent content:	
• Water:	98.9 %
• VOC (EC)	0.00 %
• Solids content:	0.6 %
• Molecular weight	18.02 g/mol
• Change in condition	
• Evaporation rate	Not determined.
• Information with regard to physical hazard classes	
• Explosives	Void
• Flammable gases	Void
• Aerosols	Void
• Oxidising gases	Void
• Gases under pressure	Void
• Flammable liquids	Void
• Flammable solids	Void
• Self-reactive substances and mixtures	Void
• Pyrophoric liquids	Void
• Pyrophoric solids	Void
• Self-heating substances and mixtures	Void
• Substances and mixtures, which emit flammable gases in contact with water	Void
• Oxidising liquids	Void
• Oxidising solids	Void
• Organic peroxides	Void
• Corrosive to metals	Void

(Contd. on page 6)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Acido Solfanilico

(Contd. of page 5)

• Desensitised explosives	Void
----------------------------------	------

10 Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
No dangerous decomposition products known.

11 Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity**
Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** Causes severe skin burns and eye damage.
 - **Serious eye damage/irritation** Causes serious eye damage.
 - **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
 - **Germ cell mutagenicity**
Based on available data, the classification criteria are not met.
 - **Carcinogenicity**
Based on available data, the classification criteria are not met.
 - **Reproductive toxicity**
Based on available data, the classification criteria are not met.
 - **STOT-single exposure**
Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure**
Based on available data, the classification criteria are not met.
 - **Aspiration hazard**
Based on available data, the classification criteria are not met.
 - **11.2 Information on other hazards**
 - **Endocrine disrupting properties**
The product contains substances, which affect the thyroid system and other hormonal systems.
- None of the ingredients is listed.

12 Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability**
No further relevant information available.
- **12.3 Bioaccumulative potential**
No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

(Contd. on page 7)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Acido Solfanilico

(Contd. of page 6)

- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Not hazardous for water.
Must not reach sewage water or drainage ditch undiluted or unneutralised.

13 Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**
Disposal must be made according to official regulations.
- **Recommended cleansing agents:**
Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|---|-----------------|
| • 14.1 UN number or ID number | |
| • ADR, IMDG, IATA | not regulated |
| • 14.2 UN proper shipping name | |
| • ADR, IMDG, IATA | not regulated |
| • 14.3 Transport hazard class(es) | |
| • ADR, ADN, IMDG, IATA | |
| • Class | not regulated |
| • 14.4 Packing group | |
| • ADR, IMDG, IATA | not regulated |
| • 14.5 Environmental hazards: | Not applicable. |
| • 14.6 Special precautions for user | Not applicable. |
| • 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| • UN "Model Regulation": | not regulated |

15 Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.

(Contd. on page 8)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Acido Solfanilico

(Contd. of page 7)

- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II**
None of the ingredients is listed.
- **REGULATION (EU) 2019/1148**
- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS** (Upper limit value for the purpose of licensing under Article 5(3))
None of the ingredients is listed.
- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**
None of the ingredients is listed.
- **Regulation (EC) No 273/2004 on drug precursors**

7647-01-0	hydrogen chloride	3
-----------	-------------------	---
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

7647-01-0	hydrogen chloride	3
-----------	-------------------	---
- **15.2 Chemical safety assessment:**
A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- **Relevant phrases**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
- **Department issuing SDS:** Product safety department.
- **Contact:** -
- **Date of previous version:** 22.03.2024
- **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Corr. 1: Skin corrosion/irritation - Category 1
Skin Irrit. 2: Skin corrosion/irritation - Category 2
Eye Dam. 1: Serious eye damage/eye irritation - Category 1
Eye Irrit. 2: Serious eye damage/eye irritation - Category 2
Skin Sens. 1: Skin sensitisation - Category 1
- *** Data compared to the previous version altered.**

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

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

- **1.1 Diagnostic Reagent**
- **Trade name:** Bilirubina Diretta - Sodio Nitrito
- **Article number:** 291083
- **CAS Number:**
7732-18-5
- **EC number:**
231-791-2
- **UFI:** F800-F0J5-800G-NAPW
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
Relevant Identified Uses: For laboratory use only
Uses advised against: Uses other than those recommended
- **Application of the substance / the mixture** Diagnostic reagent
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Sclavo Diagnostics International
Via Po 26-28, Loc. Pian dei Mori
CAP: 53018 - SOVICILLE - (SI)
ITALY
- **Further information obtainable from:** Product safety department.
- **1.4 Emergency telephone number:** +39 0577 390 444 / 445

2 Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**
7732-18-5 water, distilled, conductivity or of similar purity

(Contd. on page 2)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Sodio Nitrito

(Contd. of page 1)

- **Identification number(s)**
- **EC number:** 231-791-2

4 First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**
Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Not required.
- **6.2 Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:**
No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
No special requirements.

(Contd. on page 3)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Sodio Nitrito

(Contd. of page 2)

- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:**
The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection** Goggles recommended during refilling

9 Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Liquid
- **Colour:** Colourless
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C (7732-18-5 water, distilled, conductivity or of similar purity)
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** Not determined.

(Contd. on page 4)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Sodio Nitrito

(Contd. of page 3)

• Viscosity:	
• Kinematic viscosity	Not determined.
• Dynamic at 20 °C:	0.952 mPas
• Solubility	
• water:	Fully miscible.
• Partition coefficient n-octanol/ water (log value)	Not determined.
• Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
• Density and/or relative density	
• Density at 20 °C:	1.00234 g/cm ³
• Relative density	Not determined.
• Vapour density	Not determined.
• 9.2 Other information	
• Appearance:	
• Form:	Fluid
• Important information on protection of health and environment, and on safety.	
• Ignition temperature:	Not determined.
• Explosive properties:	Product does not present an explosion hazard.
• Solvent content:	
• Water:	99.8 %
• VOC (EC)	0.00 %
• Solids content:	0.2 %
• Molecular weight	18.02 g/mol
• Change in condition	
• Evaporation rate	Not determined.
• Information with regard to physical hazard classes	
• Explosives	Void
• Flammable gases	Void
• Aerosols	Void
• Oxidising gases	Void
• Gases under pressure	Void
• Flammable liquids	Void
• Flammable solids	Void
• Self-reactive substances and mixtures	Void
• Pyrophoric liquids	Void
• Pyrophoric solids	Void
• Self-heating substances and mixtures	Void
• Substances and mixtures, which emit flammable gases in contact with water	Void
• Oxidising liquids	Void
• Oxidising solids	Void
• Organic peroxides	Void
• Corrosive to metals	Void
• Desensitised explosives	Void

IE

(Contd. on page 5)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Sodio Nitrito

(Contd. of page 4)

10 Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
No dangerous decomposition products known.

11 Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity**
Based on available data, the classification criteria are not met.
 - **LD/LC50 values relevant for classification:**
- | ATE (Acute Toxicity Estimates) | | |
|--------------------------------|------|--------------|
| Oral | LD50 | 42,500 mg/kg |
- **Primary irritant effect:**
 - **Skin corrosion/irritation**
Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation**
Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
 - **Germ cell mutagenicity**
Based on available data, the classification criteria are not met.
 - **Carcinogenicity**
Based on available data, the classification criteria are not met.
 - **Reproductive toxicity**
Based on available data, the classification criteria are not met.
 - **STOT-single exposure**
Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure**
Based on available data, the classification criteria are not met.
 - **Aspiration hazard**
Based on available data, the classification criteria are not met.
 - **11.2 Information on other hazards**
 - **Endocrine disrupting properties**
The product contains substances, which affect the thyroid system and other hormonal systems.
- None of the ingredients is listed.

12 Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability**
No further relevant information available.
- **12.3 Bioaccumulative potential**
No further relevant information available.

(Contd. on page 6)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Sodio Nitrito

(Contd. of page 5)

- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.

13 Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:**
Disposal must be made according to official regulations.
- **Recommended cleansing agents:**
Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|---|-----------------|
| • 14.1 UN number or ID number | |
| • ADR, IMDG, IATA | not regulated |
| • 14.2 UN proper shipping name | |
| • ADR, IMDG, IATA | not regulated |
| • 14.3 Transport hazard class(es) | |
| • ADR, ADN, IMDG, IATA | |
| • Class | not regulated |
| • 14.4 Packing group | |
| • ADR, IMDG, IATA | not regulated |
| • 14.5 Environmental hazards: | Not applicable. |
| • 14.6 Special precautions for user | Not applicable. |
| • 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| • UN "Model Regulation": | not regulated |

IE

(Contd. on page 7)

Safety data sheet
according to Regulation (EC) No 1907/2006,
Article 31 including amending Regulation
EU/2020/878

Printing date 20.01.2025

Version number 1

Revision: 11.06.2024

Trade name: Bilirubina Diretta - Sodio Nitrito

(Contd. of page 6)

15 Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II**
None of the ingredients is listed.
- **REGULATION (EU) 2019/1148**
- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
None of the ingredients is listed.
- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**
None of the ingredients is listed.
- **Regulation (EC) No 273/2004 on drug precursors**
None of the ingredients is listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
None of the ingredients is listed.
- **15.2 Chemical safety assessment:**
A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- **Department issuing SDS:** Product safety department.
- **Contact:** -
- **Date of previous version:** 31.08.2023
- **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route
(European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
- *** Data compared to the previous version altered.**