

1 Identification

- **Product identifier**
- **Trade name:** BILIRUBIN TOTAL 4+1 Reagent 1
- **Article number:** BITO-5XXX
- **Synonyms** BILIRUBIN TOTAL 4+1 R1
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**
 Reagent for IN VITRO diagnostic
 Product included in kit(s) :
 - Kit composed of two reagents : BITO-0250
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
 ELITech Clinical Systems SAS
 Zone Industrielle
 61500 Sées • France
 Tel : +33 (0)2 33 81 21 00
 Fax : +33 (0)2 33 28 77 51
 www.elitechgroup.com
 MSDS.ECS-SAS@elitechgroup.com
- **Information department:** Product safety department
- **Emergency telephone number:** Contact your distributor or poison control center in your country.


2 Hazard(s) identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008** The product is not classified, according to the CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 -**
- **Hazard pictograms -**
- **Signal word -**
- **Hazard statements -**
- **Additional information:**
 Contains sulphanilic acid. May produce an allergic reaction.
 Safety data sheet available on request.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:**
 Mixture of substances.
 Aqueous solution.

Dangerous components:

CAS: 121-57-3 EINECS: 204-482-5 Index number: 612-014-00-X	sulphanilic acid	 Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	< 0.5%
--	------------------	---	--------

4 First-aid measures

- **Description of first aid measures**
- **General information:**
 Take off contaminated clothing and wash it before reuse.
 Show this safety data sheet to the doctor in attendance.
- **After inhalation:**
 Supply fresh air.
 Move out of dangerous area.
 If required, provide artificial respiration.
 If symptoms appear, seek medical advice.
- **After skin contact:**
 Take off contaminated clothing and wash before reuse.
 Immediately rinse with water.
 If symptoms appear, seek medical advice.
- **After eye contact:**
 Protect unharmed eye.
 Remove contact lenses, if present and easy to do.
 Rinse opened eye for several minutes under running water. If symptoms appear, seek medical advice.
- **After swallowing:**
 Never give anything by mouth to an unconscious person.
 Rinse out mouth.
 Seek advice from a doctor or a poison control center.
- **Most important symptoms and effects, both acute and delayed** The most important known symptoms and effects are described in sections 2 and 11.

Safety Data Sheet

acc. to OSHA HCS

Printing date 16.04.2019

Reviewed on 16.04.2019

Trade name: BILIRUBIN TOTAL 4+1 Reagent 1

(Contd. of page 1)

· **Indication of any immediate medical attention and special treatment needed** Call a person trained in first aid / a doctor.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Use fire fighting measures that suit the environment.
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** Dangerous decomposition products may be formed.
- **Advice for firefighters**
- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Wear protective clothing.
Take off contaminated clothing and wash before reuse.
Avoid physical contact with material.
Avoid formation of vapour / mist / spray.
Avoid breathing mist/vapours/spray.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb spillage to prevent material damage.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Clean the affected area carefully.
- **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

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Avoid formation of vapour / mist / spray.
Avoid breathing mist/vapours/spray.
Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
May be corrosive to metals.
Keep only in original container.
Store in a cool location.
- **Information about storage in one common storage facility:** Store away from incompatible materials (see section 10).
- **Further information about storage conditions:**
Store receptacle in a well ventilated area.
Keep container tightly closed.
Protect the product from light. Avoid exposure to heat.
- **Recommended storage temperature:** 2-8 °C
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Take off contaminated clothing and wash before reuse.
Wash hands before breaks and at the end of work.
Avoid physical contact with material.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 16.04.2019

Reviewed on 16.04.2019

Trade name: BILIRUBIN TOTAL 4+1 Reagent 1

(Contd. of page 2)

Avoid formation of vapour / mist / spray.

Avoid breathing mist/vapours/spray.

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

· **Breathing equipment:**

Under good ventilation/exhaustion at the workplace, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **Protection of hands:**



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

to be checked prior to the application.

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **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 protection:**

Goggles recommended during refilling.

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Liquid

Color: Colorless

· **Odor:** Characteristic

· **Odor threshold:** Not determined.

· **pH-value at 20 °C (68 °F):** 2.7

· **Change in condition**

Melting point: Not applicable.

Boiling point/Boiling range: Not determined.

Solidification point: Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable

· **Ignition temperature:** Not determined.

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Vapor pressure:** Not determined.

· **Density:**

Relative density at 20 °C (68 °F) 1.001 g/cm³ (8.3533 lbs/gal)

Vapor density Not determined.

Evaporation rate Not determined.

· **Solubility in / Miscibility with**

Water: Miscible

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic: Not determined.

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** May be corrosive to metals.

· **Chemical stability** Stable under recommended storage conditions.

· **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.

· **Conditions to avoid** No further relevant information available.

(Contd. on page 4)

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 16.04.2019

Reviewed on 16.04.2019

Trade name: BILIRUBIN TOTAL 4+1 Reagent 1

(Contd. of page 3)

- **Incompatible materials:**
Metals.
Bases.
- **Hazardous decomposition products:** Dangerous decomposition products may be formed.
- **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:** Based on available data, the classification criteria are not met.
 - **LD/LC50 values that are relevant for classification:**
- | |
|----------------------------------|
| 121-57-3 sulphanilic acid |
| Oral LD50 12300 mg/kg (rat) |
- **Primary irritant effect:**
 - **on the skin:** Based on available data, the classification criteria are not met.
 - **on the eye:** Based on available data, the classification criteria are not met.
 - **Sensitization:**
IF ON SKIN (or hair):
Contains sulphanilic acid. May produce an allergic reaction.
 - **Additional toxicological information:**
 - **IARC (International Agency for Research on Cancer)** None of the ingredient is in reportable quantity.
 - **NTP (National Toxicology Program)** None of the ingredient is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** At present there are no ecotoxicological assessments.
- **Persistence and degradability** Data not available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** Data not available.
- **Mobility in soil** Data not available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Disposal procedures have to be respected, see Section 13.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Primary packaging:** Plastic vial (composed of polyethylene high density)

14 Transport information

· UN-Number · DOT, ADR, ADN, IMDG, IATA	Not applicable. -
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	-
· Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA · Class	-
· Packing group · DOT, ADR, IMDG, IATA	-
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	-

-USA-

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 16.04.2019

Reviewed on 16.04.2019

Trade name: **BILIRUBIN TOTAL 4+1 Reagent 1**

(Contd. of page 4)

15 Regulatory information

- **SARA**
- *Section 302/304 (40CFR355.30 / 40CFR355.40)*: None of the ingredient is in reportable quantity.
- *Section 313 (Specific toxic chemical listings)*: Not regulated.
- **TSCA (Toxic Substances Control Act)**: This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- **Proposition 65**
- *Chemicals known to cause cancer*: None of the ingredients is listed.
- *Chemicals known to cause reproductive toxicity for females*: None of the ingredients is listed.
- *Chemicals known to cause reproductive toxicity for males*: None of the ingredients is listed.
- *Chemicals known to cause developmental toxicity*: None of the ingredient is listed.
- **Carcinogenic categories**
- *EPA (Environmental Protection Agency)* None of the ingredient is listed.
- *TLV (Threshold Limit Value established by ACGIH)* None of the ingredient is in reportable quantity.
- *NIOSH-Ca (National Institute for Occupational Safety and Health)* None of the ingredient is listed.
- *OSHA-Ca (Occupational Safety & Health Administration)* None of the ingredient is listed.
- **U. S. State Regulations:**
- **PA-RTK** None of the ingredient is in reportable quantity.
- **NJ-RTK** None of the ingredient is in reportable quantity.
- **MA-RTK** None of the ingredient is in reportable quantity.
- **RI-RTK** None of the ingredient is in reportable quantity.
- **US Federal Regulation** This mixture is a component of an FDA-regulated IN VITRO diagnostic medical device.
- **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.

- **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:** Product safety department
- **Abbreviations and acronyms:**
- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- ACGIH: American Conference of Governmental Industrial Hygienists
- 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)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- NOEC : No Observed Effect Concentration
- EC50: Effective concentration, 50 percent
- IC50 : Inhibitory concentration, 50 percent.
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- *** Data compared to the previous version altered.**

1 Identification

- **Product identifier**
- **Trade name:** **BILIRUBIN TOTAL & DIRECT 4+1 Reagent 2**
- **Article number:** BITD-6XXX
- **Synonyms** BILIRUBIN TOTAL & DIRECT 4+1 R2
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**
 Reagent for IN VITRO diagnostic
 Product included in kit(s) :
 - Kit composed of two reagents : BITO-0250 ; BIDI-0250
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
 ELITech Clinical Systems SAS
 Zone Industrielle
 61500 Sées • France
 Tel : +33 (0)2 33 81 21 00
 Fax : +33 (0)2 33 28 77 51
 www.elitechgroup.com
 MSDS.ECS-SAS@elitechgroup.com
- **Information department:** Product safety department
- **Emergency telephone number:** Contact your distributor or poison control center in your country.

2 Hazard(s) identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008** The product is not classified, according to the CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 -**
- **Hazard pictograms -**
- **Signal word -**
- **Hazard statements -**

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:**
 Mixture of substances.
 Aqueous solution.
- **Dangerous components:** No dangerous component in reportable quantity.

4 First-aid measures

- **Description of first aid measures**
- **General information:** Show this safety data sheet to the doctor in attendance.
- **After inhalation:**
 Supply fresh air.
 Move out of dangerous area.
 If required, provide artificial respiration.
 If symptoms appear, seek medical advice.
- **After skin contact:**
 Rinse with water.
 If symptoms appear, seek medical advice.
- **After eye contact:**
 Protect unharmed eye.
 Remove contact lenses, if present and easy to do.
 Rinse opened eye for several minutes under running water. If symptoms appear, seek medical advice.
- **After swallowing:**
 Never give anything by mouth to an unconscious person.
 Rinse out mouth.
 Seek advice from a doctor or a poison control center.
- **Most important symptoms and effects, both acute and delayed** Data not available.
- **Indication of any immediate medical attention and special treatment needed** Call a person trained in first aid / a doctor.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
 Use fire fighting measures that suit the environment.
 CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Safety Data Sheet

acc. to OSHA HCS

Printing date 16.04.2019

Reviewed on 16.04.2019

Trade name: BILIRUBIN TOTAL & DIRECT 4+1 Reagent 2

(Contd. of page 1)

- **Special hazards arising from the substance or mixture**
Dangerous decomposition products may be formed.
Carbon oxides (COx)
- **Advice for firefighters**
- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Wear protective clothing.
Avoid physical contact with material.
- **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).
Clean the affected area carefully.
- **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

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
· *Requirements to be met by storerooms and receptacles:* Store in a cool location.
· *Information about storage in one common storage facility:* Not required.
· *Further information about storage conditions:*
Keep container tightly closed.
Protect the product from light. Avoid exposure to heat.
· *Recommended storage temperature:* 2-8 °C
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

57-50-1 sucrose (≤ 2.5%)

PEL (USA)	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL (USA)	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV (USA)	Long-term value: 10 mg/m ³

· **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Wash hands before breaks and at the end of work.
Avoid physical contact with material.
The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- **Breathing equipment:**
Under good ventilation/exhaustion at the workplace, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- **Protection of hands:**



Protective gloves

(Contd. on page 3)

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 16.04.2019

Reviewed on 16.04.2019

Trade name: BILIRUBIN TOTAL & DIRECT 4+1 Reagent 2

(Contd. of page 2)

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

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **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 protection:**

Goggles recommended during refilling.

Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Liquid

Color: Colorless

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value at 20 °C (68 °F):** 6.2

· **Change in condition**

Melting point: Not applicable.

Boiling point/Boiling range: Not determined.

Solidification point: Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable

· **Ignition temperature:** Not determined.

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Vapor pressure:** Not determined.

· **Density:**

Relative density at 20 °C (68 °F) 1 g/cm³ (8.345 lbs/gal)

Vapor density Not determined.

Evaporation rate Not determined.

· **Solubility in / Miscibility with**

Water: Miscible

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic: Not determined.

· **Solvent content:**

VOC content: 0.6 %

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** See § Possibility of hazardous reactions.

· **Chemical stability** Stable under recommended storage conditions.

· **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** Data not available.

· **Hazardous decomposition products:**

Dangerous decomposition products may be formed.

Carbon oxides (COx)

· **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:** Based on available data, the classification criteria are not met.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 16.04.2019

Reviewed on 16.04.2019

Trade name: BILIRUBIN TOTAL & DIRECT 4+1 Reagent 2

(Contd. of page 3)

- *Primary irritant effect:*
- *on the skin:* Based on available data, the classification criteria are not met.
- *on the eye:* Based on available data, the classification criteria are not met.
- *Sensitization:* Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- *IARC (International Agency for Research on Cancer)* None of the ingredient is in reportable quantity.
- *NTP (National Toxicology Program)* None of the ingredient is listed.

12 Ecological information

- **Toxicity**
- *Aquatic toxicity:* At present there are no ecotoxicological assessments.
- **Persistence and degradability** Data not available.
- **Behavior in environmental systems:**
- *Bioaccumulative potential* Data not available.
- *Mobility in soil* Data not available.
- **Additional ecological information:**
- **General notes:**
- Generally not hazardous for water
- Prevent seepage into sewage system, workpits and cellars.
- Disposal procedures have to be respected, see Section 13.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Primary packaging:** Plastic vial (composed of polyethylene high density)

14 Transport information

· UN-Number	Not applicable.
· <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· UN proper shipping name	
· <i>DOT, ADR, ADN, IMDG, IATA</i>	-
· Transport hazard class(es)	
· <i>DOT, ADR, ADN, IMDG, IATA</i>	
· <i>Class</i>	-
· Packing group	
· <i>DOT, ADR, IMDG, IATA</i>	-
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	-

15 Regulatory information

- **SARA**
- *Section 302/304 (40CFR355.30 / 40CFR355.40):* None of the ingredient is in reportable quantity.
- *Section 313 (Specific toxic chemical listings):* Not regulated.
- **TSCA (Toxic Substances Control Act):** This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- **Proposition 65**
- *Chemicals known to cause cancer:* None of the ingredients is listed.
- *Chemicals known to cause reproductive toxicity for females:* None of the ingredients is listed.
- *Chemicals known to cause reproductive toxicity for males:* None of the ingredients is listed.
- *Chemicals known to cause developmental toxicity:* None of the ingredient is listed.
- **Carcinogenic categories**
- *EPA (Environmental Protection Agency)* None of the ingredient is listed.

· *TLV (Threshold Limit Value established by ACGIH)*

57-50-1 | sucrose

A4

- *NIOSH-Ca (National Institute for Occupational Safety and Health)* None of the ingredient is listed.
- *OSHA-Ca (Occupational Safety & Health Administration)* None of the ingredient is listed.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 16.04.2019

Reviewed on 16.04.2019

Trade name: **BILIRUBIN TOTAL & DIRECT 4+1 Reagent 2**

(Contd. of page 4)

- **U. S. State Regulations:**
- **PA-RTK** None of the ingredient is in reportable quantity.
- **NJ-RTK** None of the ingredient is in reportable quantity.

· MA-RTK

57-50-1	sucrose
---------	---------

- **RI-RTK** None of the ingredient is in reportable quantity.
- **US Federal Regulation** This mixture is a component of an FDA-regulated IN VITRO diagnostic medical device.
- **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.

- **Department issuing SDS:** Product safety department
- **Contact:** Product safety department

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

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

NOEC : No Observed Effect Concentration

EC50: Effective concentration, 50 percent

IC50 : Inhibitory concentration, 50 percent.

- * **Data compared to the previous version altered.**

USA