Safety Data Sheet
acc. to OSHA HCS

Printing date 05/18/2015 Reviewed on 05/18/2015

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1: Identification

· **Product identifier**

· ***Trade name:*** **BILIRUBIN DIRECT 4+1 Reagent 1**

· *Article number:* BIDI-5XXX
· *Synonyms* BILIRUBIN DIRECT 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 : 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.

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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.

· ***Classification according to Directive 67/548/EEC or Directive 1999/45/EC***

Xi; Irritant

R36/37/38: Irritating to eyes, respiratory system and skin.
· *Information concerning particular hazards for human and environment:*
The product has to be labeled due to the calculation procedure of international guidelines.
· *Classification system:*
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **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.

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3: Composition/information on ingredients

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

· ***Dangerous components:***

· CAS NO. Description		%	
121-57-3	sulphanilic acid	Xi R36/38-43 Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	< 1.0%
7647-01-0	hydrochloric acid	C R34; Xi R37 Skin Corr. 1B, H314; STOT SE 3, H335	< 0.5%

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4: First-aid measures

· **Description of first aid measures**
· ***General information:***
Show this safety data sheet to the doctor in attendance.
Take off contaminated clothing and wash it before reuse.
· ***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.

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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 immediate advice from a doctor or a poison control center.
· ***Information for doctor:***
· *Most important symptoms and effects, both acute and delayed* Data not available
· *Indication of any immediate medical attention and special treatment needed* Data not available

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5: Fire-fighting measures

· **Extinguishing media**
· ***Suitable extinguishing agents:***
CO_2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture** Formation of toxic gases is possible during heating or in case of fire.
· **Advice for firefighters**
· ***Protective equipment:*** As in any fire, wear a respiratory protective device, and full protective gear.

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6: Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
Prevent formation of aerosols.
· **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
· **Methods and material for containment and cleaning up:**
Use neutralizing agent.
Absorb spillage to prevent material damage.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Clean the affected area carefully.
Send for recovery or disposal in suitable receptacles.
· **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.

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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 gas/mist/vapours.
Avoid breathing gas/mist/vapours.
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:*
Keep receptacle tightly sealed.
Protect the product from light. Avoid exposure to heat.
· *Recommended storage temperature:* 2-8 °C
· **Specific end use(s)** No further relevant information available.

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8: Exposure controls/personal protection

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

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· **Control parameters**

· ***Components with limit values that require monitoring at the workplace:***	
7647-01-0 hydrochloric acid	
PEL	Ceiling limit value: 7 mg/m³, 5 ppm
REL	Ceiling limit value: 7 mg/m³, 5 ppm
TLV	Ceiling limit value: 2.98 mg/m³, 2 ppm

· *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.
Avoid physical contact with material.
Avoid formation of gas/mist/vapours.
Wash hands before breaks and at the end of work.
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 normal conditions, 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
Use equipement 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

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9: Physical and chemical properties

· **Information on basic physical and chemical properties**	
· ***General Information***	
· *Appearance:*	
Form:	Liquid
Color:	Colorless
· *Odor:*	Odorless
· *Odour threshold:*	Not determined.
· ***pH-value at 20 °C (68 °F):***	~ 1
· ***Change in condition***	
Melting point/Melting range:	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)
Vapour density	Not determined
Evaporation rate	Not determined

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· ***Solubility in / Miscibility with***	
Water:	Miscible
· ***Partition coefficient (n-octanol/water):***	Not determined
· ***Viscosity:***	
Dynamic:	Not determined
· **Other information**	Data not available

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10: Stability and reactivity

· **Reactivity** See § Possibility of hazardous reactions.
· **Chemical stability** Stable under recommended storage conditions.
· ***Thermal decomposition / conditions to be avoided:*** No decomposition if used according to specifications.
· **Possibility of hazardous reactions**
Reactions possible with:
Incompatible materials
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:**
Metals.
Strong oxidizing agents.
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:***
LD/LC50 values that are relevant for classification:

ATE (Acute Toxicity Estimates)		
Oral	LD50	> 5000 mg/kg (-)

121-57-3 sulphanilic acid		
Oral	LD50	12300 mg/kg (rat)
7647-01-0 hydrochloric acid		
Oral	LD50	900 mg/kg (rabbit)
Inhalative	LC50/1h	4.5 mg/l (rat)

· *Primary irritant effect:*
· *on the skin:* May cause irritating effect.
· *on the eye:* May cause irritating effect.
· *Inhalation:*
May be harmful by inhalation.
May cause irritating effect.
· *Ingestion:*
May be harmful if swallowed.
May cause irritations or burns of mucous.
· *Sensitization:* Contains sulphanilic acid. May produce an allergic reaction.
· ***Additional toxicological information:***
· *Carcinogenic categories*

· *IARC (International Agency for Research on Cancer)*		
7647-01-0	hydrochloric acid	3

· *NTP (National Toxicology Program)* None of the ingredient is listed.
· *CMR effects*
· *Carcinogenic effects:* Data not available
· *Mutagenicity:* Data not available
· *Reproductive Effects:* Data not available
· *Effects on development:* Data not available
· *Target organs:* Data not available
· **Aspiration hazard :** Data not available

*
12: Ecological information

· **Toxicity**
· ***Aquatic toxicity:***
Information on components:

121-57-3 sulphanilic acid	
EC50/48h	86 mg/l (Daphnia)
LC50/96h	100 mg/l (Pimephales promelas)

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· **Persistence and degradability** Data not available
· **Behavior in environmental systems:**
· ***Bioaccumulative potential*** Data not available
· ***Mobility in soil*** Data not available
· **Ecotoxical effects:**
· ***Remark:*** Can lead to changes in pH and deterioration of aquatic life.
· **Additional ecological information:**
· ***General notes:***
At present there are no ecotoxicological assessments.
Generally not hazardous for water
Can lead to changes in pH and deterioration of aquatic life.
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
· ***DOT, ADR, ADN, IMDG, IATA***	-
· **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:**	
· ***Marine pollutant:***	No
· **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":**	-

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15: Regulatory information

· ***SARA***

· *Section 302/304 (40CFR355.30 / 40CFR355.40):*	
7647-01-0	hydrochloric acid

· *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)*		
7647-01-0	hydrochloric acid	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.
· **U. S. State Regulations:**

· ***PA-RTK***	
7647-01-0	hydrochloric acid

· ***NJ-RTK***	
7647-01-0	hydrochloric acid

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· ***MA-RTK***	
7647-01-0	hydrochloric acid

· ***RI-RTK***	
7647-01-0	hydrochloric acid

· **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.

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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*
H314 Causes severe skin burns and eye damage.
H335 May cause respiratory irritation.

R34 Causes burns.
R37 Irritating to respiratory system.

· **Department issuing SDS:** Product safety department
· **Contact:** Product safety department
· ***Abbreviations and acronyms:***
SVHC : Substances of Very High Concern
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)
NOEC : No Observed Effect Concentration
EC50: Effective concentration, 50 percent
IC50 : Inhibitory concentration, 50 percent.
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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

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1: Identification

· **Product identifier**

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

· *Article number:* BITD-6XXX
· *Synonyms* BILIRUBIN TOTAL & DIRECT 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.

· ***Classification according to Directive 67/548/EEC or Directive 1999/45/EC*** Not applicable.
· *Information concerning particular hazards for human and environment:*
The product does not have to be labeled due to the calculation procedure of international guidelines.
· *Classification system:*
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **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 dangereous component in reportable quantity.

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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.
· ***Information for doctor:***
· *Most important symptoms and effects, both acute and delayed* Data not available

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· *Indication of any immediate medical attention and special treatment needed* Data not available

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5: Fire-fighting measures

· **Extinguishing media**
· ***Suitable extinguishing agents:***
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
· **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Carbon oxides (COx)
· **Advice for firefighters**
· ***Protective equipment:*** As in any fire, wear a respiratory protective device, and full protective gear.

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6: Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Ensure adequate ventilation
Prevent formation of aerosols.
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, 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 gas/mist/vapours.
Avoid breathing gas/mist/vapours.
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 receptacle tightly sealed.
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	
PEL	Long-term value: 15* 5** mg/m³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m³

· *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.

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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 normal conditions, 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
Use equipement 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
· *Odour threshold:*	Not determined.
· ***pH-value at 20 °C (68 °F):***	~ 5
· ***Change in condition***	
Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Not determined.
Solidification point:	Not determined
· ***Flash point:***	Not determined
· ***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.
· ***Density:***	
Relative density at 20 °C (68 °F)	1.007 g/cm³ (8.403 lbs/gal)
Vapour 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:	0.1 %
· **Other information**	No further relevant information available.

*
10: Stability and reactivity

· **Reactivity** See § Possibility of hazardous reactions.
· **Chemical stability** Stable under recommended storage conditions.
· ***Thermal decomposition / conditions to be avoided:*** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
· **Conditions to avoid** No further relevant information available.

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· **Incompatible materials:**
Strong oxidizing agents.
Bases.
· **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:

ATE (Acute Toxicity Estimates)		
Oral	DL50	> 5000 mg/kg (rat)

· *Primary irritant effect:*
· *on the skin:* May cause irritating effect.
· *on the eye:* May cause irritating effect.
· *Inhalation:*
May cause irritating effect.
May be harmful by inhalation.
· *Ingestion:* May be harmful if swallowed.
· *Sensitization:* No sensitizing effects known.
· ***Additional toxicological information:***
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
· *Carcinogenic categories*
· *IARC (International Agency for Research on Cancer)* None of the ingredient is listed.
· *NTP (National Toxicology Program)* None of the ingredient is listed.
· *CMR effects*
· *Carcinogenic effects:* Data not available
· *Mutagenicity:* Data not available
· *Reproductive Effects:* Data not available
· *Effects on development:* Data not available
· *Target organs:* Data not available
· **Aspiration hazard :** Data not available

*
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 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it 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**	Not applicable
· ***DOT, ADR, ADN, IMDG, IATA***	-
· **UN proper shipping name**	
· ***DOT, ADR, ADN, IMDG, IATA***	-

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/18/2015 Reviewed on 05/18/2015

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

(Contd. of page 4)

· **Transport hazard class(es)**	
· ***DOT, ADR, ADN, IMDG, IATA***	
· *Class*	-
· **Packing group**	
· ***DOT, ADR, IMDG, IATA***	-
· **Environmental hazards:**	
· ***Marine pollutant:***	No
· **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":**	-

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15: Regulatory information

· ***SARA***
· *Section 302/304 (40CFR355.30 / 40CFR355.40):* None of the ingredients is listed.
· *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.
· **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.

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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)
NOEC : No Observed Effect Concentration
EC50: Effective concentration, 50 percent
IC50 : Inhibitory concentration, 50 percent.

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