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Zone Industrielle
61500 Sées
France
Tel: +33 (0)2 33 81 21 00
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IMPORTANT INFORMATION CONCERNING MATERIAL SAFETY DATA SHEET / SAFETY DATA SHEET

Cher client,

Le 1^{er} Janvier 2013, le nom notre société SEPPIM S.A.S. change pour devenir ELITech Clinical Systems SAS. Toute notre documentation est en cours de révision pour prendre en compte ce changement de nom. Ceci inclut les Fiches de Données de Sécurité (FDS) fournies pour nos réactifs.

Les renseignements suivants de nos FDS sont modifiés à partir du 1^{er} Janvier 2013 comme indiqué ci-après:

Producteur/fournisseur :

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
MSDS.ECS-SAS@elitechgroup.com

Dear customer,

On 1st January 2013, the manufacturing company SEPPIM S.A.S. name changes to ELITech Clinical Systems SAS. All the documentation is in revision in light of the change of our company name. This includes the (Material) Safety Data Sheets ((M)SDSs) provided for our reagents.

The following contact information relative to (M)SDSs are modified from 1st January 2013 as indicated hereafter :

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
MSDS.ECS-SAS@elitechgroup.com

Product Safety Department


ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

21.12.2011

Kit Components

Product code	Description
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BITO-0XXX	BILIRUBIN TOTAL 4+1 (Kit) BITO-0201/0250/0600
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Components:

BITO-5XXX	BILIRUBIN TOTAL 4+1 - R1
BITD-6XXX	BILIRUBIN TOTAL & DIRECT 4+1 - R2

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

- **Product identifier**
- **Trade name:** BILIRUBIN TOTAL 4+1 - R1
- **Article number:** BITO-5XXX
- **Application of the substance / the preparation** Reagent for IN VITRO diagnostic
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
SEPPIM S.A.S.
4 Rue Auguste Mottin
F-61500 Sées
FRANCE
Tel: +33 2 33 81 21 00
Fax: +33 2 33 28 77 51
seppim.msds@elitechgroup.com
- **Information department:** Product safety department
- **Emergency telephone number:** Contact your distributor or poison control center in your country.

2 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of substances.
- **Dangerous/non-dangerous components:**

CAS NO.	Description	%
	alkyltrimethylammonium bromide	≤ 2.5%
121-57-3	sulphanilic acid	< 1.0%
7647-01-0	hydrochloric acid	< 0.5%

3 Hazards identification

- **Classification of the substance or mixture**
- **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 labelled 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 EU guidelines:**
The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals.
- **Special labelling of certain preparations:**
Contains sulphanilic acid. May produce an allergic reaction.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



4 First aid measures

- **General information:** Show this safety data sheet to the doctor in attendance.
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
If required, provide artificial respiration.
- **After skin contact:**
Rinse with water.
If symptoms appear, seek medical advice.
- **After eye contact:** 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.

Material Safety Data Sheet

acc. to ISO/DIS 11014

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Trade name: BILIRUBIN TOTAL 4+1 - R1

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- **Information for doctor:** Treat symptomatically.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Firefighting measures

- **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.
- **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**
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Send for recovery or disposal in suitable receptacles.
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**
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.
- **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:** 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.
- **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.

7647-01-0 hydrochloric acid (< 0.5%)

PEL	Short-term value: C 7 mg/m ³ , C 5 ppm
REL	Short-term value: C 7 mg/m ³ , C 5 ppm
TLV	Short-term value: C 2.98 mg/m ³ , C 2 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.
- **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.
- **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 respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- **Protection of hands:**
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

(Contd. on page 3)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/21/2011

Reviewed on 12/21/2011

Trade name: BILIRUBIN TOTAL 4+1 - R1

(Contd. of page 2)

- *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.

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **General Information**

- **Appearance:**

Form: Fluid

Color: Colorless

- **Odor:** Characteristic

- **pH-value at 20°C (68 °F):** ~ 2.5

- **Change in condition**

Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable.

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

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

- **Density at 20°C (68 °F):** 1 g/cm³ (8.345 lbs/gal)

- **Solubility in / Miscibility with Water:** Miscible

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

- **Solvent content:**

VOC content: 0.1 %

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

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

- **Possibility of hazardous reactions** No dangerous reactions known.

- **Incompatible materials:** Strong oxidizing agents, acids, 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

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

Not determined

121-57-3 sulphanilic acid

Oral	LD50	12300 mg/kg (rat)
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7647-01-0 hydrochloric acid

Oral	LD50	900 mg/kg (rabbit)
------	------	--------------------

Inhalative	LC50/1h	4.5 mg/l (rat)
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- **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:** Sensitizing effect is possible.

- **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

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.

USA

(Contd. on page 4)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/21/2011

Reviewed on 12/21/2011

Trade name: BILIRUBIN TOTAL 4+1 - R1

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12 Ecological information

· *Acquatic toxicity:*

Not determined

121-57-3 sulphanilic acid

EC50/48h 86 mg/l (Daphnia)

LC50/96h 100 mg/l (Pimephales promelas)

· *Persistence and degradability* Date not available

· *Behavior in environmental systems:*

· *Bioaccumulative potential* Date not available

· *Additional ecological information:*

· *General notes:*

At present there are no ecotoxicological assessments.

Disposal procedures have to be respected, see Section 13.

Water hazard class 2 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

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.

· *Recommended cleansing agent:* Water, if necessary with cleansing agents.

· *Primary packaging:* Plastic vial (composed of polyethylene high density).

14 Transport information

· *UN-Number*

· *DOT, ADR, ADN, IMDG, IATA*

-

· *UN proper shipping name*

· *DOT, ADN, IMDG, IATA*

-

· *ADR*

-

· *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.

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 ingredients is listed.

· *Carcinogenic categories*

· *EPA (Environmental Protection Agency)*

None of the ingredients is listed.

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USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/21/2011

Reviewed on 12/21/2011

Trade name: BILIRUBIN TOTAL 4+1 - R1

(Contd. of page 4)

· IARC (International Agency for Research on Cancer)

7647-01-0 hydrochloric acid

3

· NTP (National Toxicology Program)

None of the ingredients 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 ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

7647-01-0 hydrochloric acid

· **Product related hazard informations:**

The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals.

· **Special labeling of certain preparations:**

Contains sulphanilic acid. May produce an allergic reaction.

· **U. S. State Regulations:**· **PA-RTK**

7647-01-0 hydrochloric acid

· **NJ-RTK**

7647-01-0 hydrochloric acid

· **MA-RTK**

7647-01-0 hydrochloric acid

· **RI-RTK**

7647-01-0 hydrochloric acid

· **US Federal Regulation** This preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

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 MSDS:** Product safety department· **Contact:** Product safety department· *** Data compared to the previous version altered.**

USA

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

- **Product identifier**
- **Trade name:** **BILIRUBIN TOTAL & DIRECT 4+1 - R2**
- **Article number:** BITD-6XXX
- **Application of the substance / the preparation** Reagent for IN VITRO diagnostic
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
SEPPIM S.A.S.
4 Rue Auguste Mottin
F-61500 Sées
FRANCE
Tel: +33 2 33 81 21 00
Fax: +33 2 33 28 77 51
seppim.msds@elitechgroup.com
- **Information department:** Product safety department
- **Emergency telephone number:** Contact your distributor or poison control center in your country.

2 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of substances.
- **Dangerous/non-dangerous components:**

CAS NO.	Description	%
7632-00-0	sodium nitrite	< 0.1%

3 Hazards identification

- **Classification of the substance or mixture**
- **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 labelled 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 EU guidelines:**
The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals.

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



4 First aid measures

- **General information:** Show this safety data sheet to the doctor in attendance.
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
If required, provide artificial respiration.
- **After skin contact:**
Rinse with water.
If symptoms appear, seek medical advice.
- **After eye contact:** 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:** Treat symptomatically.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/21/2011

Reviewed on 12/21/2011

Trade name: BILIRUBIN TOTAL & DIRECT 4+1 - R2

(Contd. of page 1)

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

5 Firefighting measures

- **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.
- **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**
Wear protective clothing.
Ensure adequate ventilation.
Avoid physical contact with material.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Send for recovery or disposal in suitable receptacles.
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**
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.
- **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:** 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.

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

57-50-1 sucrose, pure

PEL	15* 5** mg/m ³ *total dust **respirable fraction
REL	10* 5** mg/m ³ *total dust **respirable fraction
TLV	10 mg/m ³

- **Additional information:** The lists that were valid during the creation were used as basis.
- **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.
- **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 respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- **Protection of hands:**
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

(Contd. on page 3)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/21/2011

Reviewed on 12/21/2011

Trade name: BILIRUBIN TOTAL & DIRECT 4+1 - R2

(Contd. of page 2)

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.

· **Body protection:** Protective work clothing

9 Physical and chemical properties

General Information

Appearance:

Form: Fluid
Color: Colorless

· **Odor:** Odorless

· **pH-value at 20°C (68 °F):** ~ 5

Change in condition

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

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

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

· **Density at 20°C (68 °F):** 1.007 g/cm³ (8.403 lbs/gal)

· **Solubility in / Miscibility with Water:** Miscible

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

Solvent content:

VOC content: 0.1 %

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

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Incompatible materials:** Strong oxidizing agents, acids, 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

Acute toxicity:

LD/LC50 values that are relevant for classification:

Not determined

7632-00-0 sodium nitrite

Oral	LD50	85 mg/kg (rat)
	LDL0	71 mg/kg (human)
Inhalative	LC50/4 h	5.5 mg/l (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:** Sensitizing effect is possible.

Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

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.

12 Ecological information

Acquatic toxicity:

Not determined

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USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/21/2011

Reviewed on 12/21/2011

Trade name: BILIRUBIN TOTAL & DIRECT 4+1 - R2

(Contd. of page 3)

7632-00-0 sodium nitrite

EC5/16h	123 mg/L (Pseudomonas putida)
EC50/48h	12.5-100 mg/l (Daphnia)
LC50/96h	0.09-0.13 mg/l (Onchorhyncus mykiss)

- **Persistence and degradability** Date not available
- **Behavior in environmental systems:**
- **Bioaccumulative potential** Date not available
- **Additional ecological information:**
- **General notes:**
Disposal procedures have to be respected, see Section 13.
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.

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.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.
- **Primary packaging:** Plastic vial (composed of polyethylene high density).

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** -
- **UN proper shipping name**
- **DOT, ADN, IMDG, IATA** -
- **ADR** -
- **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.

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.

All ingredients are listed.

· **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 ingredients is listed.

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

(Contd. on page 5)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/21/2011

Reviewed on 12/21/2011

Trade name: BILIRUBIN TOTAL & DIRECT 4+1 - R2

(Contd. of page 4)

· *NTP (National Toxicology Program)*

None of the ingredients is listed.

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

57-50-1 | sucrose, pure

A4

· *NIOSH-Ca (National Institute for Occupational Safety and Health)*

7632-00-0 | sodium nitrite

· *OSHA-Ca (Occupational Safety & Health Administration)*

All ingredients are listed.

· **Product related hazard informations:**

The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals.

· **U. S. State Regulations:**· **PA-RTK**

7632-00-0 | sodium nitrite

· **NJ-RTK**

7632-00-0 | sodium nitrite

· **MA-RTK**

7632-00-0 | sodium nitrite

· **RI-RTK**

7632-00-0 | sodium nitrite

· **US Federal Regulation** This preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

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 MSDS:** Product safety department· **Contact:** Product safety department· * **Data compared to the previous version altered.**

USA