ALFA WASSERMANN
Diagnostic Technologies, LLC

# SAFETY DATA SHEET

## SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

| | |
|---|---|
| **Product name** | Direct Bilirubin Reagent |
| **Catalog number** | SA1007 |
| **Product use** | For the quantitative determination of direct bilirubin concentration in serum and lithium heparin plasma. |
| **Company name** | Alfa Wassermann Diagnostic Technologies, LLC |
| **Company address** | 4 Henderson Drive<br>West Caldwell, New Jersey 07006 |
| **Country** | USA |
| **Telephone number** | 1-800-220-4488 |
| **Fax number** | 1-973-276-0383 |
| **Email** | info@alfawassermannus.com |
| **Website** | www.AWDT.us |
| **Emergency telephone number** | Toll Free: 1-866-419-ALFA (2532) |

## SECTION 2 – HAZARDS IDENTIFICATION

**Hazard classification**

**Direct Bilirubin Reagent:** This product is considered hazardous according to OSHA 29 CFR 1910.1200.

**Direct Bilirubin Sodium Nitrite Reagent:** This product is not hazardous according to OSHA 29 CFR 1910.1200.

**GHS label elements**



**Signal word**

**Direct Bilirubin Reagent:** Danger and Corrosive

**General Hazard**

**Direct Bilirubin Reagent:** Danger. Causes skin and eye burns. Prolonged exposure may cause chronic effects.

**Direct Bilirubin Sodium Nitrite Reagent:** Health injuries are not known or expected under normal use.

**Potential health effects**

**Routes of exposure**

**Direct Bilirubin Reagent:** Inhalation. Ingestion. Skin contact. Eye contact.

**Direct Bilirubin Sodium Nitrite Reagent:** Skin contact. Eye contact.

**Other hazards**

| Routes of exposure | Direct Bilirubin Reagent | Direct Bilirubin Sodium Nitrite Reagent |
|---|---|---|
| Eyes | Causes eye burns. | May cause eye irritation. |
| Skin | Causes skin burns. | May cause skin irritation. |
| Inhalation | In high concentrations, mists/vapors may irritate throat and respiratory system and cause coughing. | In high concentrations, vapors may be irritating to the respiratory system. |
| Ingestion | Can burn mouth, throat and stomach. | May cause discomfort if swallowed. |
| **Chronic effects** | Prolonged skin contact may defat the skin and produce dermatitis. | No data available. |

## SECTION 3 – COMPOSITION/ INFORMATION ON INGREDIENTS

| Hazardous Ingredients | CAS Number | % |
|---|---|---|
| **Direct Bilirubin Reagent** | | |
| Hydrochloric acid | 7647-01-0 | 1 - 2 |
| Sulphanilic acid | 121-57-3 | <1 |
| **Direct Bilirubin Sodium Nitrite Reagent** | There are no ingredients as hazardous according to OSHA 29 CFR 1910.1200. | |

## SECTION 4 – FIRST AID MEASURES

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| **Skin contact** | Remove contaminated clothing and wash with soap and plenty of water. Seek medical attention. |
| **Eye contact** | Immediately flush with plenty of water or eye wash solution for up to ten minutes. Seek medical attention. |
| **Inhalation** | Remove victim to fresh air. Seek medical attention. |
| **Ingestion** | Wash out mouth thoroughly with water. Seek medical attention. |

## SECTION 5 – FIRE-FIGHTING MEASURES

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|---|---|
| **Flammable** | No |
| **Hazardous combustion products** | **Direct Bilirubin Reagent:** Hydrogen chloride gas.<br>**Direct Bilirubin Sodium Nitrite Reagent:** None known. |
| **Extinguishing media** | Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire. |
| **Protection of firefighters** | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| **Firefighting instructions** | Use standard firefighting procedures and consider the hazards of other involved materials. |

## SECTION 6 – ACCIDENTAL RELEASE MEASURES

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|---|---|
| **Personal precautions** | Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing gloves appropriate protective clothing. Ensure adequate ventilation and treat material as you would hazardous materials. |
| **Environmental precautions** | Do not allow to enter drains, sewers or watercourses. |
| **Methods for containment and cleaning up** | Absorb spill with vermiculite or other inert material. Place in suitable container for prompt disposal. Label the container as potentially hazardous. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g., a fresh 1:10 dilution of common household bleach. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations. |

## SECTION 7 – HANDLING AND STORAGE

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|---|---|
| **Handling** | Wear safety glasses, disposable gloves and protective clothing. Wash thoroughly after handling. Handle and open container with care. |
| **Storage** | Store at 18-26°C. |

## SECTION 8 – EXPOSURE CONTROL/ PERSONAL PROTECTION

**Exposure limits**

**Direct Bilirubin Reagent**

| Components | Type | Value |
|---|---|---|
| Hydrochloric acid (CAS 7647-01-0) | Ceiling | 2 ppm |

**Personal protective equipment** ☑ Gloves ❒ Respirator ☑ Eye ❒ Footwear ☑ Clothing ❒ Other

## SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

| Properties | Direct Bilirubin Reagent | Direct Bilirubin Sodium Nitrite Reagent |
|---|---|---|
| Physical state | Liquid. | Liquid. |
| Color | Clear, colorless. | Clear, colorless. |
| Odor | No data available. | No data available. |
| Odor threshold | Not available. | Not available. |
| pH | <1 | 7 |
| Vapor pressure | Not available. | Not available. |
| Vapor density | Not available. | Not available. |
| Boiling point | Not available. | Not available. |
| Melting point/ Freezing point | Not available. | Not available. |
| Solubility in water | Soluble | Soluble |
| Specific gravity | 1.01 | 1.02 |

## SECTION 10 – STABILITY AND REACTIVITY

| | Direct Bilirubin Reagent | Direct Bilirubin Sodium Nitrite Reagent |
|---|---|---|
| **Chemical stability** | Stable under normal conditions. | Stable under normal conditions. |
| **Incompatible materials** | Strong bases. | No data available. |
| **Hazardous decomposition products** | Hydrogen chloride gas. | None known. |
| **Conditions to avoid** | None | No data available. |
| **Possibility of hazardous reactions** | Hazardous polymerization does not occur. | Hazardous polymerization does not occur. |

## SECTION 11 – TOXICOLOGICAL INFORMATION

**Toxicological data**

**Direct Bilirubin Reagent**

| Components | Test Results |
|---|---|
| Hydrochloric acid (CAS 7647-01-0) | Acute Inhalation LC50 Rat: 3124 mg/l, 1 hour<br>Acute Oral LD50 Rabbit: 900 mg/kg |

| | Direct Bilirubin Reagent | Direct Bilirubin Sodium Nitrite Reagent |
|---|---|---|
| **Sensitization** | The product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals in contact with skin. | Not classified. |
| **Acute effects** | Hydrochloric acid solutions can readily release high concentrations of hydrogen chloride gas, which is very toxic and corrosive and poses a serious inhalation hazard. | May cause discomfort if swallowed. |
| **Local effects** | Irritating to respiratory system. | Ingestion may cause irritation and malaise. |
| **Chronic effects** | Prolonged skin contact may defat the skin and produce dermatitis. | No data available. |
| **Carcinogenicity** | Not classifiable as carcinogenicity to human. | Not classifiable as carcinogenicity to human. |

## SECTION 12 – ECOLOGICAL INFORMATION

**Ecotoxicological data**

**Direct Bilirubin Reagent**

| Components | Test Results |
|---|---|
| Hydrochloric acid (CAS 7647-01-0) | Aquatic Fish LC50 Western mosquitofish (Gambusia affinis): 282 mg/l, 96 hours |

| | |
|---|---|
| **Ecotoxicity** | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. |

## SECTION 13 – DISPOSAL CONSIDERATIONS

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| **Waste disposal** | Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/ standard precautions.<br><br>Dispose in accordance with all applicable regulations. |

## SECTION 14 – TRANSPORT INFORMATION

| | **Direct Bilirubin Reagent** | **Direct Bilirubin Sodium Nitrite Reagent** |
|---|---|---|
| **DOT/IATA/IMDG/TDG** | UN 3264<br>Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric acid solution) | Not regulated. |

## SECTION 15 – REGULATORY INFORMATION

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|---|---|
| **US federal regulations** | **Direct Bilirubin Reagent:** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.<br>**Direct Bilirubin Sodium Nitrite Reagent:** This product is not hazardous as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. |
| **Hazard symbol** | **Direct Bilirubin Reagent:** Danger and corrosive |
| **Warnings** | **Direct Bilirubin Reagent:** Corrosive |

## SECTION 16 – OTHER INFORMATION

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|---|---|
| **Supplier's notes** | This safety data sheet has been complied, controlled and approved in accordance with the regulations in force. It is the user's responsibility to determine the suitability of this information for the adoption of necessary safety precautions. We reserve the right to revise the Safety Data Sheet periodically as new information becomes available. |
| **Recommended restrictions on use** | For in vitro diagnostic use only. |
| **Disclaimer of expressed and implied warranties** | Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representation as to the accuracy or completeness of the information contained herein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a determination as to the suitability of the information for their particular purposes. |
| **Preparation information** | P/N 701197-15 Rev D 7/14 |

**END OF SDS**