

## 1. Product and Company Identification

Material name	DIRECT BILIRUBIN Sodium Nitrite Reagent (R2)
Version #	01
Issue date	04-18-2013
Revision date	-
Supersedes date	-
CAS #	N/A
Kit number	906706-38
Product use	For the IN VITRO quantitative measurement of bilirubin (direct) concentration in serum.
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042
Emergency Telephone Numbers	Americas 1-760-476-3962
	Europe, Middle East & Africa +1-760-476-3961
	Asia Pacific +1-760-476-3960
	Access code 333512

## 2. Hazards Identification

Physical state	Liquid.
Appearance	Clear, colorless liquid.
Emergency overview	Health injuries are not known or expected under normal use.
OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	In high concentrations, vapors may be irritating to the respiratory system.
Ingestion	May cause discomfort if swallowed.
Target organs	Eyes.
Chronic effects	No data available.
Signs and symptoms	Direct contact with skin and eyes may cause irritation.
Potential environmental effects	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.

## 3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

## 4. First Aid Measures

### First aid procedures

Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Ingestion	If material is ingested, immediately contact a poison control center.
Notes to physician	Provide general supportive measures and treat symptomatically.

## 5. Fire Fighting Measures

<b>Flammable properties</b>	This product is not flammable.
<b>Extinguishing media</b>	
<b>Suitable extinguishing media</b>	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
<b>Unsuitable extinguishing media</b>	None known.
<b>Protection of firefighters</b>	
<b>Specific hazards arising from the chemical</b>	None known.
<b>Protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>Hazardous combustion products</b>	None known.

## 6. Accidental Release Measures

<b>Personal precautions</b>	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
<b>Environmental precautions</b>	Do not allow to enter drains, sewers or watercourses.
<b>Methods for containment</b>	Absorb spillage with non-combustible, absorbent material.
<b>Methods for cleaning up</b>	Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
<b>Other information</b>	Clean up in accordance with all applicable regulations.

## 7. Handling and Storage

<b>Handling</b>	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. Observe good industrial hygiene practices.
<b>Storage</b>	Store at 18 - 26°C. Store in a closed container away from incompatible materials.

## 8. Exposure Controls / Personal Protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Exposure guidelines</b>	Follow standard monitoring procedures.
<b>Engineering controls</b>	Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.
<b>Personal protective equipment</b>	
<b>Eye / face protection</b>	Wear approved safety glasses or goggles.
<b>Skin protection</b>	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
<b>Respiratory protection</b>	Under normal conditions, respirator is not normally required.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical & Chemical Properties

<b>Appearance</b>	Clear, colorless liquid.
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Colorless.
<b>Odor</b>	No data available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	7
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.

<b>Boiling point</b>	Not available.
<b>Melting point/Freezing point</b>	Not available.
<b>Solubility (water)</b>	Soluble.
<b>Specific gravity</b>	1.02
<b>Flash point</b>	Not available.
<b>Flammability limits in air, upper, % by volume</b>	Not available.
<b>Flammability limits in air, lower, % by volume</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.

## 10. Chemical Stability & Reactivity Information

<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Conditions to avoid</b>	No data available.
<b>Incompatible materials</b>	No data available.
<b>Hazardous decomposition products</b>	None known.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.

## 11. Toxicological Information

<b>Sensitization</b>	Not classified.
<b>Acute effects</b>	May cause discomfort if swallowed.
<b>Local effects</b>	Ingestion may cause irritation and malaise.
<b>Chronic effects</b>	No data available.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.
<b>Epidemiology</b>	No epidemiological data is available for this product.
<b>Mutagenicity</b>	Not classified.
<b>Reproductive effects</b>	Not classified.
<b>Symptoms and target organs</b>	Direct contact with skin and eyes may cause irritation.
<b>Further information</b>	No other specific acute or chronic health impact noted.

## 12. Ecological Information

<b>Ecotoxicity</b>	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.
<b>Environmental effects</b>	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulation / Accumulation</b>	Not available.
<b>Mobility in environmental media</b>	The product is completely soluble in water.

## 13. Disposal Considerations

<b>Disposal instructions</b>	Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
<b>Waste from residues / unused products</b>	Dispose in accordance with all applicable regulations.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. Transport Information

### DOT

Not regulated as a hazardous material by DOT.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

**TDG**

Not regulated as dangerous goods.

## 15. Regulatory Information

**US federal regulations**

This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)**

None

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****Hazard categories**

Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**Section 302 extremely hazardous substance (40 CFR 355, Appendix A)**

No

**SARA 311/312 Hazardous chemical**

No

**Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)**

Not controlled

**Canadian regulations**

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

**WHMIS status**

Non-controlled

**Inventory status**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

<b>State regulations</b>	This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.
<b>US - California Proposition 65 - Carcinogens &amp; Reproductive Toxicity (CRT): Listed substance</b>	Not listed.
<b>US. Massachusetts RTK - Substance List</b>	Not regulated.
<b>US. New Jersey Worker and Community Right-to-Know Act</b>	Not regulated.
<b>US. Pennsylvania RTK - Hazardous Substances</b>	Not regulated.
<b>Mexico regulations</b>	This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

## 16. Other Information

<b>Recommended restrictions</b>	Use in accordance with supplier's recommendations.
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 0 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 0 Flammability: 0 Instability: 0
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