

1. Product and Company Identification

Material name DIRECT BILIRUBIN Reagent (R1)
Version # 02
Issue date 02-22-2013
Revision date 04-18-2013
Supersedes date 04-18-2013
CAS # Mixture
Product code 202-S7
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
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 Access code 333512

2. Hazards Identification

Physical state Liquid.
Appearance Clear and colorless liquid.
Emergency overview DANGER
 Causes skin and eye burns. Prolonged exposure may cause chronic effects.
OSHA regulatory status This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects
Routes of exposure Inhalation. Ingestion. Skin contact. Eye contact.
Eyes This product causes eye burns.
Skin Causes skin burns.
Inhalation In high concentrations, mists/vapors may irritate throat and respiratory system and cause coughing.
Ingestion Can burn mouth, throat, and stomach.
Target organs Eyes. Respiratory system. Skin. Gastro-intestinal tract
Chronic effects Prolonged skin contact may defat the skin and produce dermatitis.
Signs and symptoms May cause burns in mucous membranes, throat, esophagus and stomach.
Potential environmental effects This material is not expected to be harmful to aquatic life.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Hydrochloric acid	7647-01-0	1 - 2
Sulphanilic acid	121-57-3	< 1

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures

Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.
Skin contact	Immediately flush thoroughly with water for at least 15 minutes. Get medical attention if irritation develops and persists.
Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Get medical attention immediately.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Notes to physician

Symptoms may be delayed.

General advice

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties This product is not flammable.

Extinguishing media

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.

Protection of firefighters

Specific hazards arising from the chemical None known.

Protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products Hydrogen chloride gas.

6. Accidental Release Measures

Personal precautions 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.

Environmental precautions Do not allow to enter drains, sewers or watercourses.

Methods for containment Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up 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.

Other information Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling 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.

Storage Store at 18 - 26°C. Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

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

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Hydrochloric acid (CAS 7647-01-0)	Ceiling	7 mg/m ³
		5 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Hydrochloric acid (CAS 7647-01-0)	Ceiling	3 mg/m ³
		2 ppm

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

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

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

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

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Hydrochloric acid (CAS 7647-01-0)	Ceiling	7.5 mg/m ³
		5 ppm

Mexico. Occupational Exposure Limit Values

Components	Type	Value
Hydrochloric acid (CAS 7647-01-0)	Ceiling	7 mg/m ³
		5 ppm

Exposure guidelines	Follow standard monitoring procedures.
Engineering controls	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Personal protective equipment	
Eye / face protection	Wear approved safety glasses or goggles.
Skin protection	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	Wear NIOSH approved respirator appropriate for airborne exposure at the point of use.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Clear and colorless liquid.
Physical state	Liquid.
Form	Clear, colorless liquid.
Color	Clear, colorless.
Odor	No data available.
Odor threshold	Not available.
pH	< 1
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.

Solubility (water)	Soluble.
Specific gravity	1.01
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Stable under normal storage and handling conditions.
Conditions to avoid	None under normal conditions.
Incompatible materials	Strong bases.
Hazardous decomposition products	Hydrogen chloride gas.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Hydrochloric acid (CAS 7647-01-0)		
Acute		
<i>Inhalation</i>		
LC50	Rat	3124 mg/l, 1 Hours
<i>Oral</i>		
LD50	Rabbit	900 mg/kg
Sensitization	The product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals in contact with skin.	
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.	
Local effects	Irritating to respiratory system.	
Chronic effects	Prolonged skin contact may defat the skin and produce dermatitis.	
Carcinogenicity	Not classified.	
ACGIH Carcinogens		
Hydrochloric acid (CAS 7647-01-0)	A4 Not classifiable as a human carcinogen.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Hydrochloric acid (CAS 7647-01-0)	3 Not classifiable as to carcinogenicity to humans.	
Epidemiology	Not available.	
Mutagenicity	No data available.	
Neurological effects	Not available.	
Reproductive effects	No data available.	
Teratogenicity	Not available.	
Symptoms and target organs	May cause burns in mucous membranes, throat, esophagus and stomach.	
Further information	No other specific acute or chronic health impact noted.	

12. Ecological Information

Ecotoxicological data

Components	Species	Test Results
Hydrochloric acid (CAS 7647-01-0)		
Aquatic		
Fish	LC50	Western mosquitofish (<i>Gambusia affinis</i>) 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.
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Aquatic toxicity	Not classified.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulation / Accumulation	Not available.
Mobility in environmental media	The product is soluble in water.

13. Disposal Considerations

Waste codes	D002: Waste Corrosive material [pH <=2 or >=12.5, or corrosive to steel]
Disposal instructions	Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency.
Waste from residues / unused products	Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT

Basic shipping requirements:

UN number	UN3264
Proper shipping name	Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric Acid solution)
Hazard class	8
Packing group	III
Environmental hazards	

Marine pollutant No

Additional information:

Special provisions	IB3, T7, TP1, TP28
Packaging exceptions	154
Packaging non bulk	203
Packaging bulk	241

IATA

UN number	UN3264
UN proper shipping name	Corrosive liquid, acidic, inorganic, n.o.s. (Hydrochloric Acid solution)
Transport hazard class(es)	8
Packing group	III
Environmental hazards	No
ERG code	8L
Special precautions for user	Read safety instructions, MSDS and emergency procedures before handling.

IMDG

UN number	UN3264
UN proper shipping name	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Hydrochloric Acid solution)
Transport hazard class(es)	8
Packing group	III
Environmental hazards	
Marine pollutant	No
EmS	F-A, S-B
Special precautions for user	Read safety instructions, MSDS and emergency procedures before handling.

TDG

UN number	UN3264
Proper shipping name	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Hydrochloric Acid solution)
Hazard class	8
Packing group	III
Marine pollutant	No
Special provisions	16

15. Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 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

Hydrochloric acid (CAS 7647-01-0)

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Hydrochloric acid (CAS 7647-01-0) 5000 lbs

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Threshold Planning Quantity

Hydrochloric acid (CAS 7647-01-0) 500 lbs

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Hydrochloric acid (CAS 7647-01-0) 1.0 %

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Hydrochloric acid (CAS 7647-01-0) Listed.

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

Hydrochloric acid: 5000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
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
Yes

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 Controlled

WHMIS classification E - Corrosive

WHMIS labeling



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

Country(s) or region	Inventory name	On inventory (yes/no)*
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).

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

Hydrochloric acid (CAS 7647-01-0) Listed.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US - New Jersey RTK - Substances: Listed substance

Hydrochloric acid (CAS 7647-01-0) Listed.

US. Massachusetts RTK - Substance List

Hydrochloric acid (CAS 7647-01-0) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Hydrochloric acid (CAS 7647-01-0) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

Hydrochloric acid (CAS 7647-01-0) Listed.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
 Health: 3*
 Flammability: 0
 Physical hazard: 0

NFPA ratings
 Health: 3
 Flammability: 0
 Instability: 0

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