

1. Product and Company Identification

Material name	DIRECT BILIRUBIN-SL Reagent (R1)
Version #	02
Issue date	02-22-2013
Revision date	04-18-2013
Supersedes date	02-25-2013
CAS #	Mixture
Kit number	247-30; 247-30-91R1; 247-50A
Product use	For the quantitative determination of Bilirubin (Direct) in serum. For In Vitro Diagnostic use only.
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962
Emergency Telephone Numbers	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 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
SULFAMIC ACID	5329-14-6	<1

Composition comments	All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.
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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	No data available.

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 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
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.
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Physical state	Liquid.
Form	Clear, colorless liquid.
Color	Clear, colorless.
Odor	No data available.
Odor threshold	Not available.
pH	1.4
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	Oxidizing agents.
Hazardous decomposition products	No data available.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
SULFAMIC ACID (CAS 5329-14-6)		
Acute		
<i>Oral</i>		
LD50	Rat	3160 mg/kg
Sensitization	No data available.	
Acute effects	Corrosive to skin and eyes.	
Local effects	Irritating to respiratory system.	
Chronic effects	Prolonged skin contact may defat the skin and produce dermatitis.	
Carcinogenicity	Not classified.	
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
SULFAMIC ACID (CAS 5329-14-6)		
Aquatic		
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>) 14.2 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. (SULFAMIC ACID)
Hazard class	8
Packing group	III
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. (SULFAMIC ACID)
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. (SULFAMIC ACID)
Transport hazard class(es)	8
Packing group	III
Environmental hazards	
Marine pollutant	No
Labels required	8
EmS	F-A, S-B
Special precautions for user	Read safety instructions, MSDS and emergency procedures before handling.

TDG

UN number	UN3264
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Proper shipping name	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULFAMIC ACID)
Hazard class	8
Packing group	III
Marine pollutant	D
Special provisions	16
Labels required	8

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

Not regulated.

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

None

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

Not listed.

US - New Jersey RTK - Substances: Listed substance

SULFAMIC ACID (CAS 5329-14-6) Listed.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

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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