MATERIAL SAFETY DATA SHEET



1. Product and Company Identification

Material name TOTAL BILIRUBIN-SL Accelerator Reagent (R1)

Version # 01

Issue date 04-18-2013

Revision date Supersedes date -

CAS # Mixture Kit number 243-10

Product use For the IN VITRO quantitative determination of Bilirubin (total) in serum.

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.

AppearanceColorless liquid.Emergency overviewWARNING

Causes eye irritation.

OSHA regulatory status This product is hazardous according to OSHA 29 CFR 1910.1200.

Potential health effects

Routes of exposure Inhalation. Ingestion. Skin contact. Eye contact.

Eyes Causes eye irritation. Exposed individuals may experience eye tearing, redness, and discomfort.

Skin May cause skin irritation.

Inhalation Vapors and mist may irritate throat and respiratory system and cause coughing.

Ingestion May cause discomfort if swallowed.

Target organs Eye

Chronic effects No data available.

Signs and symptoms Ingestion may cause irritation and malaise.

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

Components	CAS#	Percent	
Isotridecanol, ethoxylated	9043-30-5	< 2	

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 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.

TOTAL BILIRUBIN-SL Accelerator Reagent (R1)
905358 Version #: 01 Revision date: - Issue date: 04-18-2013

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.

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

None known.

Protection of firefighters

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

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

Carbon monoxide and carbon dioxide.

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.

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

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 General hygiene

In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment. Handle in accordance with good industrial hygiene and safety practice.

considerations

9. Physical & Chemical Properties

Appearance Colorless liquid.

Physical state Liquid. **Form** Liquid. Color Colorless, clear. Odor None known. **Odor threshold** Not available.

pН 8.5

Not available. Vapor pressure Vapor density Not available. **Boiling point** Not available. Not available. Melting point/Freezing point Soluble. Solubility (water) 1.01 Specific gravity

Flash point Not available. Not available. Flammability limits in air,

upper, % by volume

Flammability limits in air, lower, % by volume

Not available.

Not available. **Auto-ignition temperature**

10. Chemical Stability & Reactivity Information

Chemical stability Material is stable under normal conditions.

Conditions to avoid Protect against direct sunlight.

Incompatible materials Strong oxidizers, strong acids, and strong bases.

Hazardous decomposition

products

Carbon oxides.

Possibility of hazardous

reactions

Polymerization will not occur.

11. Toxicological Information

Sensitization Not classified.

Acute effects May cause discomfort if swallowed.

Local effects Causes eye irritation. **Chronic effects** No data available.

Carcinogenicity Not classifiable as to carcinogenicity to humans. **Epidemiology** No epidemiological data is available for this product.

Not classified. Mutagenicity No data available. Reproductive effects

Symptoms and target organs Ingestion may cause irritation and malaise.

Further information No other specific acute or chronic health impact noted.

12. Ecological Information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. **Environmental effects**

Not classified. **Aquatic toxicity**

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation / Not available. Accumulation

Mobility in environmental

The product is soluble in water.

media

CPH MSDS NA TOTAL BILIRUBIN-SL Accelerator Reagent (R1)

13. Disposal Considerations

Disposal instructions Dispose in accordance with all applicable regulations. Contaminated instruments and surfaces

should be disinfected in accordance with your employer's chemical-specific and universal/standard

precautions.

Waste from residues / unused

products

Dispose in accordance with all applicable regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

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 hazardous according to OSHA 29 CFR 1910.1200.

All components are on the U.S. EPA TSCA Inventory List.

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 - 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

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 D2B - Other Toxic Effects-TOXIC

WHMIS labeling



Inventory status

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

Australian Inventory of Chemical Substances (AICS) Australia

Canada Domestic Substances List (DSL) Yes

TOTAL BILIRUBIN-SL Accelerator Reagent (R1) 905358 Version #: 01 Revision date: - Issue date: 04-18-2013

4/5

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)	No
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	Yes

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

Inventory name

(PICCS)

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.

Country(s) or region

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 restrictionsUse in accordance with supplier's recommendations. **Further information**Use in accordance with supplier's recommendations.

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

HMIS® ratings Health: 1

Flammability: 0 Physical hazard: 0

NFPA ratings Health: 1

Flammability: 0 Instability: 0

DisclaimerThe information above is provided in good faith. It is believed to be accurate and represents the

best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF

SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if

Sekisui Diagnostics has been advised of the possibility of such damages.

CPH MSDS NA

On inventory (yes/no)*

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).