

IMPORTANT NOTICE CONCERNING MATERIAL SAFETY DATA SHEET/SAFETY DATA SHEET INFORMATION

Dear Valued Customer,

Sekisui Diagnostics (formerly Genzyme Diagnostics) is working to update all existing documentation in light of the change to our company name and corporate ownership. This includes the (Material) Safety Data Sheets ((M)SDSs) provided with our products.

The following contact information relative to (M)SDSs has changed effective immediately:

Corporate Headquarters:

Sekisui Diagnostics, LLC
31 New York Avenue
Framingham, MA 01701 USA
www.sekisuidiagnostics.com
Phone: 800-332-1042

Manufacturer:

Sekisui Diagnostics P.E.I. Inc.
70 Watts Avenue
Charlottetown, Prince Edward Island
C1E 2B9, Canada
www.sekisuidiagnostics.com
Phone: 800-565-0265

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

Please feel free to use the information provided above to contact us with any questions pertaining to (M)SDSs.

Material Safety Data Sheet

1 PRODUCT IDENTIFICATION AND USE

MANUFACTURER: Genzyme Diagnostics P.E.I. Inc.
70 Watts Avenue
West Royalty Industrial Park
Charlottetown, P.E.I.
Canada C1E 2B9
+1-902-566-1396

PRODUCT NAME: Total Bilirubin Assay
CATALOGUE NUMBER: 202-04, 204-S7
PRODUCT USE: For the IN VITRO quantitative determination of bilirubin (total) in serum.
DATE OF MSDS PREPARATION: September 18, 2008
MSDS PREPARED BY: John Gabriel
EMERGENCY TELEPHONE NO.: 1- (902) 566-1396

2 COMPOSITION, INGREDIENT INFORMATION

<u>COMPONENT</u>	<u>CAS REGISTRY NUMBER</u>	<u>ACGIH TLV</u>
Total Bilirubin Reagent (R1)		
Dimethyl sulfoxide 50.6% w/w	67-68-5	not established
Hydrogen chloride 0.55% w/w	7647-01-0	C2 ppm
Total Bilirubin Sodium Nitrite Reagent (R2)	not applicable	not applicable

3 HAZARDOUS IDENTIFICATION

EMERGENCY OVERVIEW:

May be harmful if swallowed. Physical and health hazard information on reagent mixtures has not been fully determined.

POTENTIAL HEALTH EFFECTS:

ROUTE OF ENTRY/EXPOSURE: EYE CONTACT: [X] SKIN CONTACT: [X] INHALATION: [X] INGESTION: [X]
SKIN ABSORPTION: [X]

EFFECTS OF ACUTE EXPOSURE TO PRODUCTS:

EYES: May cause irritation.
SKIN: May cause irritation.
INHALATION: May cause irritation to mucous membranes and upper respiratory tract.
INGESTION: May be harmful if ingested.

EFFECTS OF CHRONIC EXPOSURE TO PRODUCT:

EVIDENCE OF CARCINOGENICITY, TERATOGENICITY, REPRODUCTIVE TOXICITY, MUTAGENICITY: No constituents recognized by IARC, ACGIH, NTP or California Proposition 65 as carcinogenic. No human data on teratogenicity, embryo toxicity or mutagenicity.

4 FIRST AID MEASURES

EYES: Flush eyes with water for at least 15 minutes and obtain medical attention.
SKIN: In case of contact, immediately flush area with plenty of water. If irritation continues seek medical attention.
INHALATION: If inhaled, remove victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and obtain medical attention.
INGESTION: If ingested, drink plenty of fluids and obtain medical attention.

5 FIRE AND EXPLOSION HAZARDS

FLAMMABLE: No

FLASH POINT: not available

FLAMMABLE LIMITS (% in Air): Lower: not available. Upper: not available

EXTINGUISHING MEDIA: As appropriate for fires in surrounding materials.

FIREFIGHTING: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

AUTOIGNITION TEMPERATURE: not available

HAZARDOUS COMBUSTION PRODUCTS: not available

EXPLOSION DATA: Sensitivity to mechanical impact: not available. Sensitivity to static discharge: not available

UNUSUAL FIRE AND EXPLOSION HAZARDS: Dimethylsulfoxide (DMSO) emits toxic fumes under fire conditions; undergoes an exothermic reaction when mixed with copper wool and trichloroacetic acid. Will flash instantly when mixed with potassium permanganate.

Reacts violently with acid halides, phosphorous trichloride and trioxide, manganese perchlorate, methyl bromide and sodium hydride. When heated above its boiling point, DMSO gives off formaldehyde methyl mercaptan and sulfur dioxide.

6 ACCIDENTAL RELEASE MEASURES

PROCEDURE TO BE FOLLOWED IN CASE OF LEAK OR SPILL: Ventilate the area. Wear appropriate personal protective equipment as specified in Section 8. Contain and recover liquid when possible. Collect liquid in an appropriate container or absorb with an inert material and place in waste container. Wash surrounding area. Dispose of spilled and contaminated material in accordance with federal, provincial, state, and local regulations.

7 HANDLING AND STORAGE

HANDLING PROCEDURES AND EQUIPMENT: Avoid contact. Do not get in eyes, on skin, or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse.

STORAGE REQUIREMENTS: 18-26 °C

INCOMPATIBILITIES: Dimethylsulfoxide is incompatible with strong oxidizing and reducing agents, phosphorous halides and acid chlorides. Protect from moisture.

HAZARDOUS DECOMPOSITION PRODUCTS: not available

8 EXPOSURE CONTROLS, PERSONAL PROTECTION

ENGINEERING CONTROLS: Local exhaust not required under normal circumstances.

PERSONAL PROTECTIVE CLOTHING (PPE): Safety glasses with side-shields, lab coat, rubber nitrile or other impermeable gloves.

RESPIRATORY PROTECTION: none required.

EXPOSURE LIMITS: not available

9 PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: All reagents are liquids

APPEARANCE: R1 is clear and colorless to pale pink. R2 is clear and colorless.

ODOUR: R1 is mildly sulfurous. R2 is odorless.

ODOUR THRESHOLD: not available

MELTING POINT: not available

BOILING POINT: not available

SPECIFIC GRAVITY: R1=1.088; R2=1.030

VAPOUR PRESSURE: not available

VAPOUR DENSITY: not available

WATER SOLUBILITY: soluble

EVAPORATION RATE: not available

pH at 25 °C: R1=5; R2=5.5

COEFFICIENT OF OIL/WATER DISTRIBUTION: not available

10 STABILITY AND REACTIVITY

STABILITY: Stable

POSSIBLE HAZARDOUS REACTIONS/CONDITIONS: not available

CONDITIONS TO AVOID: not available

MATERIALS TO AVOID: not available

HAZARDOUS DECOMPOSITION PRODUCTS: not available.

11 TOXICOLOGICAL INFORMATION

LD₅₀:

Dimethyl sulfoxide 14500-28300 mg/kg, oral rat

Hydrogen chloride 900 mg/kg, oral rabbit

SENSITIZATION TO PRODUCT: not available

NAME OF TOXICOLOGICALLY SYNERGISTIC PRODUCTS: not available

IRRITANCY OF PRODUCT: not available

EVIDENCE OF CARCINOGENICITY, TERATOGENICITY, REPRODUCTIVE TOXICITY, MUTAGENICITY: no data available

12 ECOLOGICAL INFORMATION

not available

13 DISPOSAL CONSIDERATIONS

RECOMMENDATION FOR DISPOSAL OF UNUSED PRODUCT: Observe all federal, provincial, state and local regulations.

RECOMMENDATION FOR DISPOSAL OF PACKAGING: Observe all federal, provincial, state and local regulations.

14 TRANSPORT INFORMATION

SPECIAL SHIPPING INFORMATION:

R1: UN1789, Hydrochloric acid solution, Class 8, Packing Group III

R2: not regulated

15 REGULATORY INFORMATION

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulation (CPR) and the MSDS contains all the information required by the CPR.

RISK PHRASES: R36/38 Irritating to eyes and skin.

SAFETY PHRASES: S24/25 Avoid contact with skin and eyes

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S27/28 After contact with skin, take off immediately

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

16 OTHER INFORMATION

The information provided on this Material Safety Data Sheet is provided in the interest of promoting safe handling of the material. While this information is believed to be correct, Genzyme Diagnostics makes no warranty in respect to any of the information disclosed. Observe all federal, provincial, state and local laws concerning health and the environment.

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