

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.

**Genzyme Diagnostics P.E.I. Inc.**

70 Watts Avenue, Charlottetown, PE Canada C1E 2B9
Tel: 800-565-0265 • 902-566-1396 • Fax: 902-628-6504
Email: sales@dclchem.com • techserve@dclchem.com • orders@dclchem.com
www.dclchem.com • www.genzymediagnosics.com

Material Safety Data Sheet

1 PRODUCT IDENTIFICATION AND USE

MANUFACTURER:

Genzyme Diagnostics PEI Inc.
70 Watts Avenue
Charlottetown, P.E.I.
Canada C1E-2B9
+1-902-566-1396

PRODUCT NAME: SPOTCHEM Control

CATALOGUE NUMBER: CAT5724

PRODUCT USE: For IN VITRO diagnostic use in quality control.

DATE OF MSDS PREPARATION: October 16, 2008

MSDS PREPARED BY: John Gabriel

EMERGENCY TELEPHONE NO.: 1- (902) 566-1396

2 COMPOSITION, INGREDIENT INFORMATION

COMPONENT

CAS REGISTRY NUMBER

ACGIH TLV

SPOTCHEM Control Serum

not applicable

not applicable

3 HAZARDOUS IDENTIFICATION

EMERGENCY OVERVIEW:

Warning: Human source material. Treat as potentially infectious. Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HBsAg, an antigen to HIV. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human blood based products should be handled in accordance with good laboratory practices using appropriate precautions.

To the best of our knowledge, none of the reagents are hazardous as defined by OSHA (US) or EU Directives. WHMIS (Canada) exempt.

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:

The reagents contain no constituents recognized by IARC, ACGIH, or NTP as carcinogenic. No human data on teratogenicity, embryo toxicity or mutagenicity. Prolonged or repeated exposure may cause an allergic reaction in certain sensitive individuals.

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

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 with a 1:10 bleach solution. 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: 2-8 °C

INCOMPATIBILITIES: not available

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: Solid

APPEARANCE: White lyophilized powder

ODOUR: Odourless

ODOUR THRESHOLD: not available

MELTING POINT: not available

BOILING POINT: not available

SPECIFIC GRAVITY: not available

VAPOUR PRESSURE: not available

VAPOUR DENSITY: not available

WATER SOLUBILITY: soluble

EVAPORATION RATE: not available

pH at 25 °C: not available

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: not available

SENSITIZATION TO PRODUCT: Prolonged or repeated exposure may cause an allergic reaction in certain sensitive individuals.

NAME OF TOXICOLOGICALLY SYNERGISTIC PRODUCTS: not available.

IRRITANCY OF PRODUCT: not 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:

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.

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, GDPEI 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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