

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

Creatinine Start Reagent (R1)

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Creatinine Start Reagent (R1)

Product Number: 265-80-91R1

Kit Number: 265-30; 265-50; 265-OP

Synonym(s): Enzymatic Creatinine Reagent (R1)

Product Use: Component of Enzymatic Creatinine Assay. For the IN VITRO quantitative determination of creatinine in serum, plasma and urine.

Description: Dilute, buffered aqueous solution containing small to trace amounts of enzyme (protein), salt, antibiotic, surfactant and preservative.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics

31 New York Avenue
Framingham, MA 01701-9322
USA

Phone: 800-332-1042

Distributor

Genzyme Diagnostics P.E.I. Inc.

70 Watts Ave.
Charlottetown, PE C1E 2B9
CANADA

Phone: 800-332-1042

Distributor

Genzyme Diagnostics

115 Summit Drive
Exton, PA 19341
USA

Phone: 800-999-6578

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

CHEMTREC (U.S.): 800-424-9300

CHEMTREC (Outside U.S.): +1 703-527-3887

Distributor

Genzyme Diagnostics

50 Gibson Drive
Kings Hill, West Malling
Kent, ME19 4AF
UK

Phone: 44 (0) 1732 220022

2. HAZARDS IDENTIFICATION

Precautionary Statements:

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. This preparation contains a small concentration of chloramphenicol which may cause cancer. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: light yellow liquid.

Routes of Exposure:

Occupational exposure routes may include eye contact, skin contact, skin absorption and inhalation.

Potential Health Effects:

Inhalation

Although there is no evidence that the enzyme(s) in this preparation induces specific respiratory hypersensitivity, all proteins are potential respiratory allergens and may result in respiratory sensitization in certain individuals after repeated and/or prolonged inhalation exposure, producing mild to severe symptoms similar to pollen allergy or asthma, including mucous membrane or eye irritation, itching of the skin or eyes, sneezing, nasal or sinus congestion, coughing, and tightness in the chest. These symptoms may develop as late as 12 hours after exposure.

Eye

Eye exposure may cause irritation, redness and watering. Eye contact may cause systemic effects.

Skin

Skin contact may cause irritation.

Ingestion

Effects of ingestion are unknown, but may include digestive system irritation, nausea, vomiting or diarrhea.



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Potential Health Effects:

Chronic Effects Exposure to chloramphenicol may cause leukemia, a cancer of the blood or bone marrow. It may disrupt the bone marrow's production of blood cells (aplastic anemia). Repeated exposure to chloramphenicol may damage the liver.

Target Organs Chloramphenicol: blood, immune system (skin) and liver.

Regulatory Status:

This preparation is not classified as hazardous under E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIPS 2009 No. 716 or U.N. GHS ST/SG/AC 10/30. This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200.

This preparation contains chloramphenicol, which is classified by IARC as 2A, probably carcinogenic to humans.

Potential Environmental Effects:

No data available.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Chloramphenicol	56-75-7	200-287-4	< 0.1
EC R-Phrases: R43, R45, R63, R68		EC Hazard Class: T	

4. FIRST AID MEASURES

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water while separating eyelids with fingers, removing contact lenses if worn. Continue to flush for at least 15 minutes. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, immediately flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.



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Specific Hazards Arising from the Chemical:

Irritating and/or toxic gases may be emitted upon the product's decomposition.

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material and avoid vapor inhalation. After handling, immediately wash any areas of the body that may have been exposed, whether or not known skin contact has occurred.

Environmental Precautions:

No information available.

Methods and Materials for Containment and Clean-Up:

Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2 - 8°C (36 - 46°F). Do not store with incompatible substances; see Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

Engineering Controls:

Minimize potential for aerosolization. Handle within a containment system, with local exhaust ventilation, or with dilution ventilation at a minimum. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory	A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, European Standard CR 529, or other applicable regulatory standards should be followed whenever exposure limits may be exceeded (if applicable) and engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant the use of respiratory protection. In such cases, a full-facepiece respirator with formaldehyde vapor cartridges selected to provide a filtration efficiency appropriate to your workplace is recommended.
Eye/Face	Wear appropriate protective chemical safety goggles.
Skin	Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over clothing to minimize contact and contamination of clothing.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Light yellow liquid	pH:	7 - 8
Odor:	Unknown	Solubility:	Water-soluble
Specific Gravity:	1 (approximate)	Vapor Pressure:	Not available
Boiling Point:	Not available	Partition Coefficient (n-octanol/water):	Not available
Melting Point:	Not applicable	Vapor Density:	Not available
Freezing Point:	Not available		
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	Not available		

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

Incompatible Materials:

Unknown.

Hazardous Decomposition Products:

Thermal decomposition can lead to release of irritating gases and vapors.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:**Toxicology Data - Selected LD50s and LC50s**

Chloramphenicol	56-75-7	Oral LD50 Rat: 2500 mg/kg
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Chronic Effects:

Chloramphenicol may induce aplastic anemia, and this condition is related to the occurrence of leukemia (HSDB).

Carcinogenicity:**IARC - Group 2A (Probably Carcinogenic to Humans)**

Chloramphenicol	56-75-7	Monograph 50 [1990] (overall evaluation upgraded from 2B to 2A with supporting evidence from other data relevant to the evaluation of carcinogenicity and its mechanisms), Supplement 7 [1987]
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NTP (National Toxicology Program) - Report on Carcinogens - Reasonably Anticipated to be Human Carcinogens

Chloramphenicol	56-75-7	Reasonably Anticipated To Be A Carcinogen
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U.S. - California - Proposition 65 - Carcinogens List

Chloramphenicol	56-75-7	carcinogen, initial date 10/1/89
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U.S. - OSHA - Hazard Communication Carcinogens

Chloramphenicol	56-75-7	Present
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Mutagenicity:

Chloramphenicol produced positive results in in vitro mutagenicity assays (EMEA).

Teratogenicity:

In teratogenicity studies in the rat and the rabbit chloramphenicol did not show teratogenic effects but caused a high incidence of fetal deaths (EMEA).

Reproductive Effects:

No data available.

Sensitization:

Chloramphenicol induced allergic contact dermatitis has been reported in medical literature.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)

Chloramphenicol	56-75-7	Present
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US State Regulations:**U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances**

Chloramphenicol	56-75-7	Present
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International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canada - WHMIS - Classifications of Substances

Chloramphenicol 56-75-7 D2A

Inventory - Australia - Inventory of Chemical Substances (AICS)

Chloramphenicol 56-75-7 Present

Inventory - Canada - Domestic Substances List (DSL)

Chloramphenicol 56-75-7 Present

Inventory - China

Chloramphenicol 56-75-7 Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Chloramphenicol 56-75-7 200-287-4

Inventory - Korea - Existing and Evaluated Chemical Substances

Chloramphenicol 56-75-7 KE-10140

Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

MSDS Origination Date: July 01, 2009

Version #: 2

Revision Date: July 06, 2009



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Disclaimer:

The 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 Genzyme 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 Genzyme has been advised of the possibility of such damages.