MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name	**Enzymatic Creatinine Reagent (R1)**
Version #	01
Issue date	01-16-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Kit number	271-80-91R1
Product use	For the IN VITRO quantitative determination of creatinine in serum, plasma and urine.
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042
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

2. Hazards Identification

Physical state	Liquid.
Appearance	Light yellow liquid.
Emergency overview	DANGER May cause allergic respiratory reaction. This preparation contains a small concentration of chloramphenicol which may cause cancer. Avoid contact with eyes and skin.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
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.
Ingestion	May cause discomfort if swallowed.
Target organs	Blood. Immune system. Liver.
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). May cause damage to the liver.
Signs and symptoms	Direct contact with skin and eyes may cause irritation.
Potential environmental effects	The product components are 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
Creatine amidinohydrolase	37340-58-2	< 5
Sarcosine oxidase	9029-22-5	< 1

Components	CAS #	Percent
Chloramphenicol	56-75-7	< 0.1

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.

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 injured person into fresh air and keep person calm under observation. If breathing is difficult, give oxygen. 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 Irritating and/or toxic gases may be emitted upon the products decomposition.

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

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 Clean up in accordance with all applicable regulations. Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water.

7. Handling and Storage

Handling Do not breathe mist or vapor. Avoid contact with skin and eyes. Persons susceptible for allergic reactions should not handle this product. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

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	Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.
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	Use a NIOSH/MSHA approved air purifying respirator as needed to control exposure. Consult with respirator manufacturer to determine respirator selection, use, and limitations. Use positive pressure, air-supplied respirator for uncontrolled releases or when air purifying respirator limitations may be exceeded. Follow respirator protection program requirements (OSHA 1910.134 and ANSI Z88.2) for all respirator use.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Light yellow liquid.
Physical state	Liquid.
Form	Liquid.
Color	Light yellow.
Odor	None known.
Odor threshold	Not available.
pH	7 - 8
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not Applicable. / Not available.
Solubility (water)	Soluble.
Specific gravity	1 Approx.
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.
Partition coefficient (n-octanol/water)	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	No data available.
Incompatible materials	No data available.
Hazardous decomposition products	Thermal decomposition can lead to release of irritating gases and vapors.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Sensitization	May cause allergic respiratory reaction.
Acute effects	May cause discomfort if swallowed.
Local effects	Ingestion may cause irritation and malaise.
Chronic effects	May cause damage to the liver.
Carcinogenicity	May cause cancer.

IARC Monographs. Overall Evaluation of Carcinogenicity

Chloramphenicol (CAS 56-75-7)	2A Probably carcinogenic to humans.

US NTP Report on Carcinogens: Anticipated carcinogen

Chloramphenicol (CAS 56-75-7) Reasonably Anticipated to be a Human Carcinogen.

Epidemiology No epidemiological data is available for this product.

Mutagenicity Not classified.

Reproductive effects Not classified.

Symptoms and target organs Direct contact with skin and eyes may cause irritiation.

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

12. Ecological Information

Ecotoxicological data

Components		Species	Test Results
Chloramphenicol (CAS 56-75-7)			
Aquatic			
Crustacea	EC50	Shrimp (Penaeus stylirostris)	> 0.05 mg/l, 48 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.

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

Bioaccumulation / Accumulation Not available.

Mobility in environmental media The product is completely soluble in water.

13. Disposal Considerations

Disposal instructions 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

DOT

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 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
Section 311/312 (40 CFR 370)	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	D2A - Other Toxic Effects-VERY TOXIC

WHMIS labeling

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
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)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Hazardous Substances (Director's): Listed substance

Chloramphenicol (CAS 56-75-7) Listed.

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

Chloramphenicol (CAS 56-75-7) Listed.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Chloramphenicol (CAS 56-75-7) Listed: October 1, 1989 Carcinogenic.

US - Pennsylvania RTK - Hazardous Substances: Special hazard

Chloramphenicol (CAS 56-75-7) Special hazard.

US. Massachusetts RTK - Substance List

Chloramphenicol (CAS 56-75-7) Listed.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Chloramphenicol (CAS 56-75-7) Listed.

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: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
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