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 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.

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	_

Enzymatic Creatinine Reagent (R1)

CPH MSDS NA

CAS# Components Percent 56-75-7 Chloramphenicol < 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

Eve contact In case of contact, immediately flush eves 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

Unsuitable extinguishing

media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

None known.

Protection of firefighters

Specific hazards arising

from the chemical

Protective equipment and precautions for firefighters Irritating and/or toxic gases may be emitted upon the products decomposition.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

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

Use standard firefighting procedures and consider the hazards of other involved materials.

protective clothing.

Environmental precautions Methods for containment

Do not allow to enter drains, sewers or watercourses. 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.

Enzymatic Creatinine Reagent (R1) CPH MSDS NA **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.

7 - 8 pН

Vapor pressure Not available. Not available. Vapor density **Boiling point** Not available.

Not Applicable. / Not available. Melting point/Freezing point

Solubility (water) Soluble. 1 Approx. Specific gravity Flash point Not available. Not available. Flammability limits in air,

upper, % by volume

Flammability limits in air,

lower, % by volume

Not available. **Auto-ignition temperature** Not available. Partition coefficient

(n-octanol/water)

10. Chemical Stability & Reactivity Information

Chemical stability Material is stable under normal conditions.

Not available.

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. May cause discomfort if swallowed. **Acute effects**

Ingestion may cause irritation and malaise. Local effects

Chronic effects May cause damage to the liver.

May cause cancer. Carcinogenicity

IARC Monographs. Overall Evaluation of Carcinogenicity

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

Enzymatic Creatinine Reagent (R1) CPH MSDS NA

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.

MutagenicityNot classified.Reproductive effectsNot 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

EcotoxicityThe 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 regulationsThis 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

Enzymatic Creatinine Reagent (R1)
904617 Version #: 01 Revision date: - Issue date: 01-16-2013

Section 302 extremely hazardous substance (40 CFR 355, Appendix A)

Section 311/312 (40 CFR Yes

370)

Drug Enforcement

Canadian regulations

Administration (DEA) (21 CFR

1308.11-15)

Not controlled

Inventory name

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS

On inventory (yes/no)*

No

5/6

contains all the information required by the CPR.

WHMIS status Controlled

WHMIS classification D2A - Other Toxic Effects-VERY TOXIC

No

WHMIS labeling



Inventory status

Country(s) or region

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	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.

Toxic Substances Control Act (TSCA) Inventory

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

Chloramphenicol (CAS 56-75-7)

(PICCS)

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

Chloramphenicol (CAS 56-75-7)

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.

United States & Puerto Rico

US. Pennsylvania RTK - Hazardous Substances

904617 Version #: 01 Revision date: - Issue date: 01-16-2013

Listed. Chloramphenicol (CAS 56-75-7)

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.

CPH MSDS NA Enzymatic Creatinine Reagent (R1)

HMIS® ratings Health: 2*

Flammability: 0 Physical hazard: 0

NFPA ratings Health: 2

Flammability: 0
Instability: 0

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 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.

Enzymatic Creatinine Reagent (R1)
904617 Version #: 01 Revision date: - Issue date: 01-16-2013