

1. Product and Company Identification

Material name	Enzymatic Creatinine R2
Version #	01
Issue date	01-16-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Kit number	265-80-91R2; 265-R2; 265-30
Product use	Component of Enzymatic Creatinine Assay. 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 brown liquid.
Emergency overview	DANGER May cause allergic respiratory reaction.
OSHA regulatory status	This product is hazardous according to OSHA 29 CFR 1910.1200.
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	Respiratory system.
Chronic effects	No data available.
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
Peroxidase	9003-99-0	5
Creatinine amidohydrolase	9025-13-2	1
Sodium azide	26628-22-8	< 0.1

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 to fresh air. For breathing difficulties, oxygen may be necessary. 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	None known.
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	None known.

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.

7. Handling and Storage

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

US. ACGIH Threshold Limit Values

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m ³
		0.11 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3	Vapor.
		0.29 mg/m3	
		0.11 ppm	Vapor.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3	
		0.11 ppm	Vapor.

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3
		0.11 ppm

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	Under normal conditions, respirator is not normally required. Wear NIOSH approved respirator appropriate for airborne exposure at the point of use.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Light brown liquid.
Physical state	Liquid.
Form	Liquid.
Color	Light brown.
Odor	Odorless.
Odor threshold	Not available.
pH	6 - 8
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Soluble.
Specific gravity	Not available.
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.

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	None known.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Sodium azide (CAS 26628-22-8)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	20 mg/kg
<i>Oral</i>		
LD50	Rat	27 mg/kg
Sensitization	May cause allergic respiratory reaction.	
Acute effects	May cause discomfort if swallowed.	
Local effects	Ingestion may cause irritation and malaise.	
Chronic effects	Inhalation may result in respiratory sensitization.	
Carcinogenicity	Not classifiable as to carcinogenicity to humans.	
ACGIH Carcinogens		
Sodium azide (CAS 26628-22-8)	A4 Not classifiable as 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 irritation.	
Further information	No other specific acute or chronic health impact noted.	

12. Ecological Information

Ecotoxicological data

Components	Species	Test Results
Sodium azide (CAS 26628-22-8)		
Aquatic		
Crustacea	EC50 Water flea (<i>Daphnia pulex</i>)	2.8 - 6.2 mg/l, 48 hours
Fish	LC50 Bluegill (<i>Lepomis macrochirus</i>)	0.68 mg/l, 96 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 hazardous according to OSHA 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.

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Sodium azide (CAS 26628-22-8) 1000 lbs

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Threshold Planning Quantity

Sodium azide (CAS 26628-22-8) 500 lbs

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium azide (CAS 26628-22-8) 1.0 %

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

Sodium azide: 1000

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) No

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

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)	Yes
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)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
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	Yes

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

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

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

Sodium azide (CAS 26628-22-8) Listed.

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

Not listed.

US - New Jersey RTK - Substances: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

US. Massachusetts RTK - Substance List

Sodium azide (CAS 26628-22-8) Listed.

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

Sodium azide (CAS 26628-22-8) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

Sodium azide (CAS 26628-22-8) 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

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.