

1. Product and Company Identification

1.1	Product name	Enzymatic Creatinine Reagent (R1 + R2)
	Substance/mixture	Mixture
	CAS #	Mixture
	Kit number	MD-101112
1.2	Recommended product use	
	Mixture's intended use	Diagnostic reagent for IN VITRO quantitative measurement of creatinine in urine.
	Product restrictions	None known
1.3	Details of the supplier of the safety data sheet	
	Manufacturer information	
	Corporate Headquarters	Diamond Diagnostics Inc.
		333 Fiske St., Holliston, MA 01746 United States of America
		www.diamonddiagnostics.com
	Telephone	+1 (508) 429-0450
	Email	support@diamonddiagnostics.com
	Distributor information	
	Distributor Headquarters	Mission Diagnostics LLC
		1 Burton Dr., Meridith, NH 03246
		United States of America
	Telephone	+1 (508) 429-0450
	Email	support@diamonddiagnostics.com
1.4	Emergency Telephone	
	Emergency Phone #	+1 (508) 429-0450

2. Hazards Identification

GHS- Classification

Classification Skin Irritant, Eye Irritant



2.1 Substance or mixture classification

Physical state	Liquid
Appearance	Yellow Solution (R1) + Brown Solution (R2)
Emergency overview	Health injuries are not known or expected under normal use.

2.2 Label Elements

Signal word	Danger
Hazardous substances	(R1) Creatine amidohydrolase, sarcosine oxidase, catalase, ascorbate oxidase. (R2) Creatininase, peroxidase, sodium azide.
OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.

2.3 Potential health effects

Routes of exposure

Skin contact. Eye contact.

Eyes

May cause eye irritation or serious eye damage.

Skin

May cause skin irritation or skin burns.

Inhalation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingestion

If swallowed, may cause discomfort and lead to gastrointestinal tract burns.

Target organs

Eyes, lungs and skin.

Chronic effects

Repeated skin contact may cause dermatitis.

Signs and symptoms

Direct contact with skin and eyes may cause irritation.

2.4 Potential environmental effects

The product components are not classified as environmentally hazardous. However, this does not eliminate the possibility that large or frequent spills can have a harmful or damaging impact on the environment.

Hazard Statements

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements

P261

Avoid breathing dust/fume/gas/mist/vapors/spray.

P284

[In case of inadequate ventilation] wear respiratory protection.

P304 + P341

If inhaled; if breathing is difficult, remove person to fresh air and keep comfortable for breathing.

P341 + P311

If experiencing respiratory symptoms, call a poison center or doctor.

P501

Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

3. Composition/Information on ingredients

Classification : Respiratory sensitization, Category 1

H334 May cause allergies or asthma symptoms or breathing difficulties if inhaled.

Components:

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Creatine amidohydrolase	CAS No 37340-58-2	Resp, Sens. 1, H334	≤ 5.0%
Oxidase, sarcosine	CAS No 9029-22-5	Resp, Sens. 1, H334	≤ 1.0%
Catalase	CAS No 9001-05-2	Resp, Sens. 1, H334	≤ 0.1%
Oxidase, ascorbate	CAS No 9029-44-1	Resp, Sens. 1, H334	≤ 0.1%
Creatininase	(CAS No) 9025-13-2	Resp. Sens. 1, H334	≤ 1.0%
Peroxidase	(CAS No) 9003-99-0	Resp. Sens. 1, H334	≤ 0.1%
Sodium Azide	(CAS No) 26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	<0.1%

4. First Aid Measures

4.1 Description of First Aid Measures

Eye Contact	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding eyelids open. Remove contact lenses immediately if worn by the affected person. Pursue medical treatment if irritation persists.
Skin Contact	In case of skin contact, remove any or all of contaminated clothing, while rinsing the affected skin with large amounts of water. Pursue medical attention if irritation develops and persists.
Inhalation	In case of inhalation, move the affected person to fresh air. Call a physician if symptoms develop or persist.
Ingestion	Do NOT induce vomiting. In case of ingestion, make the affected person either drink some water or rinse out their mouth. If any other symptoms persist, contact a medical professional or a poison control center.
Notes to Physician	Provide general supportive measures and treat symptomatically.
General Advice	If you feel unwell, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Eye Contact	(R1) Causes serious eye damage (R2) May cause slight irritation
Skin Contact	Causes skin irritation
Inhalation	(R1) Causes corrosion of the breathing system. (R2) May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Ingestion	Causes corrosion of the digestion system

5. Fire-Fighting Measures

5.1 Flammable properties This product is not flammable.

5.2 Extinguishing media

Suitable extinguishing media

Extinguish with water spray, carbon dioxide (CO₂), dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media

No limitations are given.

5.3 Protection of firefighters

Specific hazards arising from the chemical

Carbon oxides
Sulfur oxides
Nitrogen oxides (NO_x)
Sodium oxides

Protective equipment and precautions for firefighters

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

Firefighting equipment/instructions

(R1) Use standard firefighting procedures and consider the hazards of other involved materials. Avoid contaminating surface water with fire extinguishing water.

(R2) Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials. Avoid contaminating surface water with fire extinguishing water.

Hazardous combustion Products

(R1) Hazardous combustion gases or vapors may develop in the event of fire.

(R2) Toxic fumes may be released in the event of fire.

6. Accidental Release Measures

- 6.1 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.
- 6.2 Environmental precautions** Avoid contamination to enter drains, sewers or watercourses.
- 6.3 Methods for containment and cleaning up**
Absorb spillage with non-combustible, absorbent material such as sand, diatomaceous earth, vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
- 6.4 Other information** Clean up in accordance with all applicable regulations.

7. Handling and Storage

- 7.1 Safe Handling** Ensure good ventilation of the work station. Wear personal protective equipment. Avoid breathing dust/fumes/gas/mist/vapors/spray.
- Hygiene Measures** Do not eat, drink or smoke when using this product. Wash exposed skin thoroughly after handling
- 7.2 Storage** Store at 2-8°C. Store in a well ventilated place. Keep cool.
- 7.3 Specific use** See section 1 – Recommended Use

8. Exposure Controls / Personnel

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Creatine amidohydrolase 37340-58-2	Not listed	Not listed	Not listed
Oxidase, sarcosine 9029-22-5	Not listed	Not listed	Not listed
Catalase 9001-05-2	Not listed	Not listed	Not listed
Oxidase, ascorbate 9029-44-1	Not listed	Not listed	Not listed
Creatininase 9025-13-2	Not listed	Not listed	Not listed
Peroxidase 9003-99-0	Not listed	Not listed	Not listed
Sodium Azide 26628-22-8	C 0.290000 mg/m3	Not listed	Not Listed

- 8.1 Occupational exposure limits**
(R1) No exposure limits noted for ingredient(s).
(R2) See table below in section 8.2 for information.
- 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.
- 8.2 Personal protective equipment**
- Eye / face protection** Wear appropriate safety glasses, goggles or face shields.

Skin protection	Wear lab coat or other protective garments. Wear protective gloves. Remove any contaminated clothing promptly.
Respiratory protection	In case of inadequate ventilation, wear respiratory protection. Avoid inhalation.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Other information	Do NOT eat, drink or smoke during use.
Environment Exposure	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Control Parameters

Enzymatic Creatinine R2
No Additional information available
Peroxidase (9003-99-0)
No Additional information available
Sodium azide (26628-22-8)
USA – ACGIH – Occupational Exposure Limits

Local Name	Sodium Azide
ACGIH OEL Ceiling	0.29 mg/m³ (as sodium azide) / 0.11 ppm (as Hydrazoic acid vapor)
Remark (ACGIH)	TLV® Basis: Card impair; lung dam. Notations: A4 (not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2023
Creatininase (9025-13-2)	
No Additional information available	

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance	Liquid
Physical state	Liquid
Form	Liquid
Color	(R1) Yellow (R2) Brown
Odor	Odorless
Odor threshold	No data available
pH	(R1) 7-8 (R2) 6-8
Vapor pressure	No data available
Vapor density	No data available
Boiling point	No data available
Viscosity (mm²/s)	No data available

Melting/Freezing point	No data available
Solubility (water)	Soluble
Specific gravity	1-1.1
Flash point	No data available
Flammability limits in air, upper, % by volume	No data available
Flammability limits in air, lower, % by volume	No data available
Decomposition temperature	No data available
Auto-ignition temperature	No data available
Evaporation rate	No data available
Relative Density	No data available
Partition coefficient: (n-octanol/water)	No data available
Explosive properties	No data available
Oxidizing properties	Not oxidizing.

10. Stability and Reactivity

10.1 Reactivity	This product is non-reactive under normal conditions of use, storage and transport.
10.2 Chemical stability	Material is stable under normal conditions.
10.3 Possibility of hazardous Reactions	No dangerous reactions known under normal conditions of use.
10.4 Conditions to avoid	No dangerous reactions known under normal conditions of use.
10.5 Incompatible materials	No data available
10.6 Hazardous decomposition Products	Under normal conditions of storage and use, hazardous decomposition products should not be produced

11. Toxicological Information

11.1 Information on toxicological effects

Sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Acute effects	Not classified.

(R1)

Catalase (9001-05-2)	
LD50 oral rat	> 5000 mg/kg

(R2)

Peroxidase (9003-99-0)	
LD50 oral rat	>2000 mg/kg
Sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rabbit	20 mg/kg

LC50 inhalation rat	0.054 – 0.52 mg/l air (EPA OPPTS 870.1300)
ATE US (oral)	27 mg/kg body weight
ATE US (dermal)	20 mg/kg body weight

Local effects	Not classified. (R1 pH 7-8, R2 pH 6-8)
Serious eye damage / irritation	Not classified (R2 pH 6-8)
Chronic effects	No data available.
Target Organ Effects	No data available.
Carcinogenicity	Not classified.
Epidemiology	No epidemiological data is available for this product.
Mutagenicity	Not classified.
Reproductive effects	Not classified.
STOP-single exposure	Not classified.
STOP-repeat exposure	Not classified.
Symptoms and target organs	May cause allergy or asthma symptoms or breathing difficulties if inhaled May cause slight eye irritation
Additional information	No other specific acute or chronic health impact noted.

12. Ecological Information

12.1 Toxicity

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.
Ecology (general)	The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment

(R1)

Catalase (9001-05-2)	
LC50 – Fish [1]	> 100 mg/l Pimephales promelas
EC50 – Crustacea [1]	95 mg/l Daphnia magna
LC50 – Fish [2]	> 3.48 mg/l Pimephales promelas
EC50 – Crustacea [2]	26.2 mg/l Daphnia magna

(R2)

Peroxidase (9003-99-0)	
EC50 – Crustacea [1]	26.2 mg/l (OECD 202: 48 h, Daphnia magna)
ErC50 - algae	176.6 mg/l (OECD 201: 72 h, Scenedesmus sp.)
Sodium azide (26628-22-8)	
LC50 – Fish [1]	2.75 mg/l Oncorhynchus mykiss (rainbow trout)
EC50 – Crustacea [1]	< 1 mg/l
EC50 – Other aquatic organisms [1]	5 mg/l (Gammarus fasciatus)

12.2 Persistence and degradability

(R1) No data is available on the degradability of this product.

(R2)

Peroxidase (9003-99-0)	
Persistence and degradability	Readily biodegradable in water

12.3 Bioaccumulation/Accumulation

(R1) No data available.

(R2)

Peroxidase (9003-99-0)	
Partition coefficient n-octanol/water (Log Pow)	-1.3 (OECD 107, 20°C)

12.4 Mobility in environmental media

(R1) No data available

(R2) The product is completely soluble in water.

13. Disposal Considerations

13.1 Disposal methods

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 local and national regulations. Avoid releasing unused products into drainage systems and/or into the environment.

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.
DOR	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
TDG	Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) Inventory except for:

(R1)

Sarcosine oxidase	CAS No 9029-22-5	≤ 1.0%
Creatine amidohydrolase	CAS No 37340-58-2	≤ 5.0%
Catalase	CAS No 9001-05-2	≤ 0.1%
Ascorbate oxidase	CAS No 9029-44-1	≤ 0.1%

Creatine amidohydrolase (37340-58-2)	
EPA TSCA Regulatory Flag	XU – XU – indicates a substance exempt from reporting under the Chemical Data reporting rule (40 CFR 711)
Catalase (9001-05-2)	
EPA TSCA Regulatory Flag	XU – XU – indicates a substance exempt from reporting under the Chemical Data reporting rule (40 CFR 711)

(R2)

Peroxidase	CAS No 9003-99-0	≤ 0.1%
Sodium azide	CAS No 26628-22-8	< 0.1%
Creatininase	CAS No 9025-13-2	≤ 1.0%

Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40CFR Part 372:

Peroxidase (9003-99-0)	
EPA TSCA Regulatory Flag	XU – XU – indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711)

Sodium azide (26628-22-8)	
CERCLA RQ	1000 lb
RQ (Reportable quantity, section 304 of EPA's List of Lists	1000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb
Creatininase (9025-13-2)	
EPA TSCA Regulatory Flag	XU – XU – indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711)

CANADA

(R1)

Sarcosine oxidase (9029-22-5)	
	Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)
Creatine amidohydrolase (37340-58-2)	
	Listed on the Canadian NDSL (Non-Domestic Substances List)
Catalase (9001-05-2)	
	Listed on the Canadian DSL (Domestic Substances List)
Ascorbate oxidase (9029-44-1)	
	Listed on the Canadian DSL (Domestic Substances List)

(R2)

Peroxidase (9003-99-0)	
	Listed on the Canadian DSL (Domestic Substances List)
Sodium azide (26628-22-8)	
	Listed on the Canadian DSL (Domestic Substances List)
Creatininase (9025-13-2)	
	Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

EU-Regulations

(R1)

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:		
Reference Code	Applicable	Entry title or description
3(b)	Enzymatic Creatinine R1	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10.

(R2)

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:		
Reference Code	Applicable	Entry title or description
3(b)	Enzymatic Creatinine R2	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10.

Contains no REACH candidate substance. Contains no REACH Annex XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance(s) subject to Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

National Regulations

(R1)

Sarcosine oxidase (9029-22-5)
Not listed on the United States TSCA (Toxic Substances Control Act) inventory
Creatine amidohydrolase (37340-58-2)
Listed on the United States TSCA (Toxic Substances Control Act) inventory – Status Active
Catalase (9001-05-2)
Listed on the United States TSCA (Toxic Substances Control Act) inventory – Status Active
Ascorbate oxidase (9029-44-1)
Not listed on the United States TSCA (Toxic Substances Control Act) inventory

(R2)

Peroxidase (9003-99-0)
Listed on the United States TSCA (Toxic Substances Control Act) inventory – Status: Active
Sodium azide (26628-22-8)
Listed on the United States TSCA (Toxic Substances Control Act) inventory – Status Active
Listed on INSQ (Mexican National Inventory of Chemical Substances)
Creatininase (9025-13-2)
Listed on the United States TSCA (Toxic Substances Control Act) inventory – Status Active

Component	State or local regulations
Sodium azide (26628-22-8)	U.S. – Delaware – Pollutant Discharge Requirements – Reportable Quantities; U.S. – New York City – Right to Know Hazardous Substances List

Additional information

No additional information available

16. Other Information

Recommended restrictions

Use in accordance with supplier's recommendations.

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Full text of H-phrases:

H300	Fatal if swallowed
H310	Fatal in contact with skin
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

NFPA ratings

Health: 2
 Flammability: 0
 Instability: 0


NFPA health hazard:

2 – Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA fire hazard:

0 – Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity:

0 – Material that in themselves are normally stable, even under fire conditions.

Hazard Rating
Health:

2 Moderate Hazard – temporary or minor injury may occur

Flammability:

0 Minimal Hazard – materials that will not burn

Physical:

0 Minimal Hazard – materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.

Personal protection:

G
 G – safety glasses, gloves, vapor respirator

Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in text.