

1. Product and Company Identification

1.1	Product name	Leukocyte Esterase R1 + R2 Reagent
	Substance/mixture	Mixture
	CAS #	Mixture
	Kit number	MD-101101
1.2	Recommended product use	
	Mixture's intended use	Diagnostic reagent for IN VITRO quantitative measurement of leukocyte esterase 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	Acute Toxicity, Eye irritation, skin irritation, aquatic Chronic, Specific target organ toxicity (Single exposure)
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2.1 Substance or mixture classification

Physical state	Liquid
Appearance	Clear/yellow
Emergency overview	Health injuries are not known or expected under normal use.

2.2 Label Elements

Signal word	Warning
Hazardous substances	Sodium Azide, ProClin 300, Ethanol
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

In high concentrations, vapors may be irritating to the upper respiratory tract leading to chemical pneumonitis and pulmonary edema.

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

Harmful to aquatic life with long-lasting effects

Hazard Statements

H302

Harmful if swallowed

H315

Causes skin irritation and eye damage

H319

Causes serious eye irritation

H335

May cause respiratory irritation

H412

Harmful to aquatic life with long-lasting effects

Precautionary Statements

P261

Avoid breathing mist/vapors/spray

P264

Wash skin thoroughly after handling

P272

Contaminated work clothing should not be allowed out of the workplace

P280

Wear protective gloves/protective clothing/eye protection/face protection

P302+P352

IF ON SKIN: Wash with plenty of water

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P333+P313

If Skin irritation or rash occurs: Get medical advice/attention

P337+P313

If eye irritation persists: Get medical advice/attention

P312

Call a POISON CENTER or doctor if you feel unwell

P501

Dispose of contents/container in accordance with local regulations

3. Composition/Information on ingredients

Components:

Chemical name	CAS-No.	Classification	Concentration (% w/w)
ProClin 300	26172-55-4 / 2682-20-4	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	0.05-0.1%

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Ethanol	64-17-5	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	3-6%
Sodium Azide	26628-22-8	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	<1.0%

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

Causes serious eye damage

Skin Contact

Causes skin irritation

Inhalation

Causes corrosion of the breathing system

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)
- Protective equipment and precautions for firefighters**
 Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
- Firefighting equipment/instructions**
 Use standard firefighting procedures and consider the hazards of other involved materials.
 Avoid contaminating surface water with fire extinguishing water.
- Hazardous combustion Products**
 No data

6. Accidental Release Measures

- 6.1 Personal precautions** Avoid contact with skin, eyes, and clothing. Ensure adequate ventilation. Use personal protective equipment.
- 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** Avoid contact with skin and eyes. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
- Hygiene Measures** Wash exposed skin thoroughly after handling.
- 7.2 Storage** Store at 2-10°C in amber bottles. Protect from light and contamination. Reclose cap tightly after each use, reduce exposure to air when not in use.
- 7.3 Specific use** See section 1 – Recommended Use

8. Exposure Controls / Personnel

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
ProClin 300 26172-55-4 / 2682-20-4	Not listed	Not listed	Not listed
Ethanol 64-17-5	1,900 mh/m3	1,900 mh/m3	1,900 mh/m3
Sodium Azide 26628-22-8	0.29 mg/m3	Not listed	Not listed

8.1 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.

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

Under normal conditions, respirator is not required.

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.

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance

Liquid

Physical state

Liquid

Form

Liquid

Color

Clear/colorless

Odor

Odorless

Odor threshold

No data available

pH

R1: 8.0-9.0

R2: 5.0-6.0

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

No data Available

Flash point	>23°C (ethanol)
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:	No data available
Explosive properties	No data available
Oxidizing properties	No data available

10. Stability and Reactivity

10.1 Reactivity	No data available
10.2 Chemical stability	Material is stable under normal conditions.
10.3 Possibility of hazardous Reactions	Hazardous polymerization does not occur.
10.4 Incompatible materials	Strong oxidizing agents, acids, heavy metals.
10.5 Hazardous polymerization	Will not occur
10.6 Conditions to avoid	Exposure to heat and light
10.7 Hazardous decomposition Products	Carbon monoxide, carbon dioxide, and nitrogen oxides. In the event of fire, refer to Section 5.3

11. Toxicological Information

11.1 Information on toxicological effects	
Sensitization	Not classified
Acute effects	May cause discomfort if swallowed.
Local effects	Ingestion may cause irritation and nausea.
Chronic effects	No data available
Target Organ Effects	No data available
Carcinogenicity	Not classified based on available information.
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.
Additional information	No other specific acute or chronic health impact noted.

12. Ecological Information

12.1 Toxicity

Ecotoxicity

The product contains components harmful to aquatic life. Avoid release into the environment.

Environmental effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

12.2 Persistence and degradability

No data is available on the degradability of this product.

12.3 Bioaccumulation/Accumulation

Not expected to bioaccumulate

12.4 Mobility in environmental media

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

This product is not hazardous according to OSHA 29CFR 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, Subpart. D)

Sodium Azide is subject to TSCA Section 12(b) export notification requirements.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated

CERCLA (Superfund) reportable quantity (lb.) (40 CFR 302.4)

Sodium Azide is listed (RQ 1000lbs)

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 (Extremely Hazardous Substances):**

Sodium azide TPQ = 500 lbs

SARA 313 (Toxic Chemicals Reporting):

Sodium azide is listed.

Hazard categories

Immediate Hazard – Yes – due to acute oral toxicity (H302)

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)

Not controlled

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

Not listed

US. Massachusetts RTK - Substance List

Sodium azide is listed

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

Sodium azide is listed

US. Pennsylvania RTK - Hazardous Substances

Sodium azide is listed

16. Other Information

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.