

1. Product and Company Identification

1.1	Product name	Leukocyte Esterase Calibrator
	Substance/mixture	Mixture
	CAS #	Mixture
	Kit numbers	MD-101201.01, MD-101201.02, MD-101201.03
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 Skin Irritant, Eye Irritant



2.1 Substance or mixture classification

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

2.2 Label Elements

Signal word	None
Hazardous substances	No data available
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.
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Eyes May cause eye irritation or serious eye damage.

Skin May cause skin irritation or skin burns.

Inhalation No data available.

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

Target organs Eyes 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

H302 Harmful if swallowed
 H317 May cause an allergic skin reaction
 H319 Causes serious eye irritation

Precautionary Statements

P261 Avoid breathing mist/vapors/spray
 P264 Wash skin thoroughly after handling.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P301 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 P337 + P313 If eye irritation persists: Get medical advice/attention.
 P302 + P352 IF ON SKIN: Wash with plenty of water.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
 P501 Dispose of contents/container to an approved waste disposal plant.

3. Composition/Information on ingredients

Additional non-hazardous components are present in this formulation and are considered trade secrets. These components do not contribute to the classification of the product under OSHA HCS (29 CFR 1910.1200).

Components:

Chemical name	CAS-No.	Concentration (% w/w)
Tris(hydroxymethyl)aminomethane	77-86-1	0.1% - 1.0%
ProClin 300	26172-55-4 / 2682-20-4	<0.1%
Esterase material	Proprietary	Trade Secret

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 No data available.

Ingestion Do NOT induce vomiting. In case of ingestion, make the affected person rinse out their mouth. If any other symptoms persist, contact a medical professional or a poison control center.

**Notes to Physician
General Advice**

Provide general supportive measures and treat symptomatically.
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	No data available
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**
No data available
- 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**
Irritating fumes in fire conditions. Carbon oxides, nitrogen oxides.

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. Ensure adequate ventilation.
- 6.2 Environmental precautions** No data available.
- 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 2-8°C. Store in a closed container away from incompatible materials.
- 7.3 Specific use** See section 1 – Recommended Use

8. Exposure Controls / Personnel

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Tris(hydroxymethyl)aminomethane 77-86-1	Not listed	Not listed	Not Listed
ProClin 300 26172-55-4 / 2682 / 2682-20-4	Not listed	Not listed	Not Listed
Esterase material	Not listed	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

No data available

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

7.0 – 8.0

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/miscible

Specific gravity

No data available

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: No data available

(n-octanol/water)

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

No data available

10.4 Conditions to avoid Avoid exposure to light and heat.

10.5 Incompatible materials Strong oxidizing agents, strong acids or bases.

10.6 Hazardous polymerization No data available

10.7 Hazardous decomposition Products

Carbon monoxide, carbon dioxide, and nitrogen oxides. In the event of fire, refer to Section 5.

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 to carcinogenicity to humans.

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. Harmful if swallowed.

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

12. Ecological Information

12.1 Toxicity

Ecotoxicity

Contains small quantities of materials 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.

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)

Not regulated.

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

Not regulated.

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

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
 Delayed Hazard - No
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

Section 302 extremely No

Hazardous substance
(40 CFR 355, Appendix
A) Section 311/312 (40
CFR370)

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 Non-controlled

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

Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	
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 Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

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

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.